Appendix P

Colorado Medical Assistance Program
Prior Authorization Procedures, Coverage Policies and Drug Utilization Criteria
Health First Colorado Pharmacy Benefit
For Physicians and Pharmacists

Drug products requiring a prior authorization for the Health First Colorado pharmacy benefit are listed in this document. Prior authorization criteria are based on FDA product labeling, CMS approved compendia, clinical practice guidelines, and peer-reviewed medical literature.

Prior Authorization Procedures:

- Prior authorizations may be called or faxed to the helpdesk at:
  Phone: 1-800-424-5725
  Fax: 1-888-424-5881
- Products qualify for a 3-day emergency supply in an emergency situation. In this case, call the helpdesk for an override.
- Prior authorization (PA) forms are available by visiting https://www.colorado.gov/hcpf/pharmacy-resources .
- PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form.
- Physicians or assistants who are acting as the agents of the physicians may request a PA by phone.
- Pharmacists from long-term-care pharmacies and infusion pharmacy must obtain a signature from someone who is authorized to prescribe drugs before they submit PA forms.
- Pharmacists from long-term-care pharmacies and infusion pharmacies can request a PA by phone if specified in the criteria.
- Please note that initiating therapy with a requested drug product, including non-preferred drugs, prior to a PA request being reviewed and approved does not necessitate approval of the PA request. This includes initiating therapy by administration in the inpatient setting, by using office samples, or by any other means.
- All PA requests are coded online into the PA system.

Early Refill Limitations:

- Non-controlled prescriptions may be refilled after 75% of previous fill is used. Controlled substance prescriptions (DEA Schedule 2 through 5) may be refilled after 85% of the previous fill is used. Synagis may be refilled after 92.5% of the previous fill is used.

Medical Supply Products and Medications:

- All supplies, including insulin needles, food supplements and diabetic supplies are not covered under the pharmacy benefit, but are covered as medical supply items through the Durable Medical Equipment (DME) benefit.
- If a medical benefit requires a PA, the PA request can be submitted through the provider application available at http://www.coloradopar.com/
- DME questions should be directed to Gainwell Technologies (Formerly DXC Technology) 1-844-235- 2387. Only policy questions regarding Durable Medical Equipment should be directed to the state at 303-866-3406.

Physician Administered Drugs and Medical Billing:

- Physician administered drugs (PADs) include any medication or medication formulation that is administered intravenously or requires administration by a healthcare professional (including cases where FDA package labeling for a medication specifies that administration should be performed by or under the direct supervision of a healthcare professional). PAD criteria listed on Appendix P apply specifically to drug products when billed through the Health First Colorado pharmacy benefit. Only PADs administered by a healthcare professional in the member's home or in a long-term care facility should be billed through the Health First Colorado pharmacy benefit (see "Physician Administered Drugs" section below). PADs administered by a healthcare professional in the office, clinic, dialysis unit, or outpatient hospital settings should be billed through the Health First Colorado medical benefit using the standard buy-and-bill process and following procedures outlined in the PAD Billing Manual (found on the PAD Resources Page at https://www.colorado.gov/hcpf/physician-administered-drugs).

Drug	Criteria	PAR Length
Drug classes that have been migrated to the Preferred Drug List (PDL) https://www.colorado.gov/hcpf/pharmacy-resources	Anticoagulants (oral), Antidepressants, Antiemetics, Antiherpetics, Antihistamines with decongestants, Antihypertensives, Antiplatelets, Atypical Antipsychotics (oral), Bisphosphonates (oral), Constipation (opioid-induced), Diabetes Management Classes, Erythropoiesis Stimulating Agents, Fibromyalgia Agents, Filgrastim/Pegfilgrastim/Sargromastim/Filgrastim-SNDZ, Fluoroquinolones, Growth Hormones, Hepatitis C Virus Treatments, Insulin, Intranasal Corticosteroids, Leukotrienes, Multiple Sclerosis Agents, Neurocognitive Disorder Agents, Ophthalmic Allergy Products, Otezla (apremilast), Overactive Bladder Agents, Pancreatic Enzymes, Proton Pump Inhibitors, Pulmonary Arterial Hypertension Therapies, Respiratory Inhalants, Sedative Hypnotics, Skeletal Muscle Relaxants, Stimulants and other ADHD Agents, Targeted Immune Modulators (self-administered), Testosterone Products, Topical Immunomodulators, Triptans	
ACETAMINOPHEN CONTAINING PRODUCT MAXIMUM DOSING	A prior authorization is required for dosages of acetaminophen exceeding 4000mg/day. Doses over 4000mg/day are not qualified for emergency 3 day supply approval	N/A
ADAKVEO (crizanlizumab-tmca)	**Adakveo** (crizanlizumab-tmca) may be approved for members meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Medication is being used to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease. Maximum dose: Adakveo 5mg/kg every 2 weeks (IV Infusion)	One year
ADUHELM (aducanumab-avwa)	**Aduhelm** (aducanumab-avwa) may be approved if the member meets ALL of the following criteria: 1. Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials, as evidenced by ALL of the following: a. Positron Emission Tomography (PET) scan OR lumbar puncture positive for amyloid beta plaque b. Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1 (available at https://otm.wustl.edu/cdr-terms-agreement/) c. Mini-Mental State Examination (MMSE) score of 24-30 OR Montreal Cognitive Assessment (moCA) Test score of 19-25 **AND** 2. Member is ≥ 50 years of age **AND** 3. The prescriber attests that member has been counseled on the approval and safety status of Aduhelm (aducanumab-avwa) being approved under accelerated approval based on reduction in amyloid beta plaques **AND** 4. Prior to initiation of Aduhelm (aducanumab-avwa), the prescriber attests that the member meets ALL of the following: a. Member has had a brain MRI within the prior one year to treatment initiation, showing no signs or history of localized superficial siderosis, ≥ 10 brain microhemorrhages, and/or brain hemorrhage > 1 cm b. Attestation that MRI will be completed prior to the 7th (1st dose at 10 mg/kg) and 12th (6th dose at 10 mg/kg) infusion **AND** 5. Member does not have any of the following:	See criteria

	a. Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive impairment including (but not limited to) stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus b. Contraindications to PET, CT scan, or MRI c. History of or increased risk of amyloid related imaging abnormalities ARIA-edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H) d. History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of Aduhelm (aducanumab-avwa) e. History of bleeding abnormalities or taking any form of anticoagulation therapy **AND** 6. Aduhelm (aducanumab-avwa) is prescribed by or in consultation with a neurologist **AND** 7. The prescribed regimen meets FDA-approved labeled dosing: a. Infusion 1 and 2: 1 mg/kg over approximately 1 hour every 4 weeks b. Infusion 3 and 4: 3 mg/kg over approximately 1 hour every 4 weeks c. Infusion 5 and 6: 6 mg/kg over approximately 1 hour every 4 weeks d. Infusion 7 and beyond: 10 mg/kg over approximately 1 hour every 4 weeks **AND** 8. To bill for Aduhelm (aducanumab-avwa) under the pharmacy benefit, the medication must be administered in the member's home or in a long-term care facility Initial approval period: 6 months Second prior authorization: an additional 6 months of Aduhelm (aducanumab-avwa) therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 7th infusion Subsequent approval: an additional 6 months of Aduhelm (aducanumab-avwa) therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 12th infusion Maximum dose: 10 mg/kg IV every 4 weeks The above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	
ALBUMIN	Albumin products may be approved if meeting the following criteria:	One year

	• Medication is given in the member's home or in a long-term care facility AND
	• Administration is for one of the following FDA-approved indications:
	  ○ Hypoproteinemia
	  ○ Burns
	  ○ Shock due to:
	  ▪ Burns
	  ▪ Trauma
	  ▪ Surgery
	  ▪ Infection
	  ○ Erythrocyte resuspension
	  ○ Acute nephrosis
	  ○ Renal dialysis
	  ○ Hyperbilirubinemia
	  ○ Erythroblastosis fetalis	

ALDURAZYME (laronidase)	**Aldurazyme** (laronidase) may be approved for members meeting the following criteria:
	• Aldurazyme (laronidase) is being administered in a long-term care facility or in a member's home by a healthcare professional AND
	• Member is 6 months of age or older AND
	• Member does not have acute febrile or respiratory illness AND
	• Member does not have progressive/irreversible severe cognitive impairment AND
	• Member has a diagnosis of Mucopolysaccharidosis, Type 1 confirmed by one of the following:
	  ○ Detection of pathogenic mutations in the IDUA gene by molecular genetic testing OR
	  ○ Detection of deficient activity of the α-L-iduronidase lysosomal enzyme
	AND
	• Member has a diagnosis of one of the following subtypes:
	  ○ Diagnosis of Hurler (severe) or Hurler-Scheie (attenuated) forms of disease OR
	  ○ Diagnosis of Scheie (attenuated) form of disease with moderate to severe symptoms
	AND
	• Alurazyme (laronidase) is being prescribed by or in consultation with a provider who specializes in inherited metabolic disorders AND
	• Member has a documented baseline value for urinary glycosaminoglycan (uGAG) AND
	• Member has a documented baseline value for one of the following based on age:
	  ○ Members ≥ 6 years of age: percent predicted forced vital capacity (FVC) and/or 6- minute walk test OR
	  ○ Members 6 months to 6 years of age: cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test
	
	<u>Reauthorization Criteria:</u>
	After one year, member may receive approval to continue therapy if meeting the following:
	• Has documented reduction in uGAG levels AND
	• Has demonstrated stability or improvement in one of the following based on age:
		One year

<table>
<tr><td></td><td>

Members ≥ 6 years of age: stability or improvement in percent predicted FVC and/or 6-minute walk test OR
Members 6 months to less than 6 years of age: stability or improvement in cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC and/or 6-minute walk test

Max dose: 0.58 mg/kg as a 3 to 4-hour infusion weekly.
</td><td></td></tr>
<tr><td>ALINIA (nitazoxanide)</td><td>
Alinia (nitazoxanide) may be approved if meeting the following criteria:

ALINIA is being prescribed for diarrhea caused by Giardia lamblia or Cryptosporidium parvum AND
Member is 1 year of age or older AND
If treating diarrhea due to C. parvum in members with Human Immunodeficiency Virus (HIV) infection, the member is receiving antiretroviral therapy AND
Prescription meets the following FDA-labeled dosing:

<table>
<tr><td>Age (years)</td><td>Dosage of Nitazoxanide</td><td>Duration</td></tr>
<tr><td>1-3</td><td>5 mL (100mg) oral suspension every 12 hours with food</td><td></td></tr>
<tr><td>4-11</td><td>10 mL (200mg) oral suspension every 12 hours with food</td><td>3 days</td></tr>
<tr><td>>11</td><td>500mg orally every 12 hours with food</td><td></td></tr>
</table>
Note: The tablet product formulation is currently not reported as an active drug in the Medicaid Drug Rebate Program (MDRP) and will not be covered until such a time that there is change made to rebate status for this product.
</td><td></td></tr>
<tr><td>ALLERGY EXTRACT PRODUCTS (Oral)</td><td>
Grastek (timothy grass pollen allergen extract):

Must be between 5 and 65 years old.
Must not be pregnant or nursing.
Must be prescribed by an allergist.
Must have a documented diagnosis to ONLY timothy grass pollen allergen extract or the Pooideae family (meadow fescue, orchard, perennial rye, Kentucky blue, and red top grasses) confirmed by positive skin test or IgE antibodies.
Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Must be willing to administer epinephrine in case of severe allergic reaction.
Must take first dose in physician’s office.
Must be started 12 weeks prior to the season if giving only seasonally.
May be taken daily for up to 3 consecutive years.

Must NOT have:

Severe, unstable or uncontrolled asthma
Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat
Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before
Been diagnosed with eosinophilic esophagitis
Allergic to any of the inactive ingredients contained in Grastek which include gelatin, mannitol, and sodium hydroxide
A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function,

</td><td>One year</td></tr>
</table>

unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.
- Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics.
- Be taken with other immunotherapy (oral or injectable)

Oralair (sweet vernal, orchard, perennial rye, timothy, kentucky blue grass mixed pollens allergen extract):

Must be between 5 and 65 years old.
Must not be pregnant or nursing.
Must be prescribed by an allergist.
Must have a documented diagnosis to ONLY Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass allergen extract confirmed by positive skin test or IgE antibodies.
Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Must be willing to administer epinephrine in case of severe allergic reaction.
Must take first dose in physician's office.

Must NOT have:
- Severe, unstable or uncontrolled asthma
- Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat
- Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before
- Been diagnosed with eosinophilic esophagitis
- Allergic to any of the inactive ingredients contained in Oralair which include mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, and lactose monohydrate.
- A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.
- Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics.
- Be taken with other immunotherapy (oral or injectable)

Ragwitek *(short ragweed pollen allergen extract):*

Must be between 18 and 65 years old.
Must be started 12 weeks prior to the season and only prescribed seasonally.
Must not be pregnant or nursing.
Must be prescribed by an allergist.
Must have a documented diagnosis to ONLY short ragweed pollen allergen extract or the Ambrosia family (giant, false, and western ragweed) confirmed by positive skin test or IgE antibodies.
Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

	Must be willing to administer epinephrine in case of a severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Ragwitek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable)	
ALPHA–1 PROTEINASE INHIBITORS	FDA approved indication if given in the member's home or in a long-term care facility: • **Aralast**: Chronic augmentation therapy in members having congenital deficiency of Alpha –1 Proteinase Inhibitor with clinically evident emphysema • **Prolastin**: Emphysema associated with Alpha-1 Antitrypsin Deficiency • **Zemaira**: Chronic augmentation and maintenance therapy in members with Alpha- 1 Proteinase Inhibitor deficiency with clinically evident emphysema	Lifetime
AMONDYS 45 (casimersen)	**Amondys 45** (casimersen) may be approved for members meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND • Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 45 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a pediatric neurologist, cardiologist, or pulmonary specialist) AND • Provider attests that serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) and glomerular filtration rate (GFR) will be measured prior to initiation of and that the member will be monitored periodically for kidney toxicity during treatment AND • The member must be on corticosteroids at baseline or prescriber provides clinical rationale for not using corticosteroids AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale or Forced Vital Capacity (FVC) documented AND • Provider and patient or caregiver are aware that continued US FDA approval of Amondys 45 (casimersen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial.	Initial: 24 weeks Continued: One year

	Reauthorization: After 24 weeks of treatment with Amondys 45 (casimersen), the member may receive approval to continue therapy for one year if the following criteria are met: • Member has shown no intolerable adverse effects related to Amondys 45 (casimersen) treatment at a dose of 30mg/kg IV once a week AND • Member has normal renal function or stable renal function if known impairment AND • Member demonstrates response to Amondys 45 (casimersen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC). Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence. Maximum Dose: 30 mg/kg per week	
ANOREXIANTS	Weight loss medications are not a covered benefit. **Adipex P** (phentermine) **Belviq** (lorcaserin) **Contrave** (naltrexone/bupropion) **Lomaira** (phentermine) **Phentermine** **Qsymia** (phentermine/topiramate ER) **Saxenda** (liraglutide) **Xenical** (Orlistat)	Weight loss drugs are not a covered benefit.
ANTI-ANEMIA MEDICATIONS	Oral prescription iron products may be approved for members with a diagnosis of iron deficient anemia (applies to products available by prescription only) Injectable anti-anemia agents (such as **Infed®**, **Ferrlecit®**, **Venofer®, Dexferrum®**) may be approved for members meeting the following criteria: • Member has a diagnosis of iron deficient anemia **AND** • Oral preparations are ineffective or cannot be used **AND** • Medication is being administered in a long-term care facility or in the member's home by a home healthcare provider Note: For coverage criteria for OTC **f**errous sulfate and ferrous gluconate, refer to "OTC Products" section.	Lifetime
ATYPICAL ANTIPSYCHOTIC INJECTABLES Abilify Maintena, Aristada, Geodon injection, Invega Sustenna, Invega Trinza, Perseris ER, Risperdal Consta, Zyprexa Relprevv	A prior authorization may be approved for when the medication is administered in a long-term care facility or in a member's home by a healthcare professional. *Oral atypical antipsychotic criteria can be found on the preferred drug list.*	One year
AVEED (testosterone undecanoate)	Claims for medications administered in a clinic or medical office are billed through the Health First Colorado medical benefit.	Product not eligible for pharmacy billing.

BACTROBAN (mupirocin) Cream and Nasal Ointment	**Bactroban Cream** (mupirocin calcium cream) must be prescribed for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in total area), impetigo, infected eczema or folliculitis caused by susceptible strains of Staphylococcus aureus and Streptococcus pyogenes. **Bactroban Nasal Ointment** (mupirocin calcium) must be prescribed for the eradication of nasal colonization with methicillin-resistant Staphylococcus aureus in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant S. aureus infection during institutional outbreaks of infections with this pathogen.	Cream: One year Nasal Ointment: Lifetime
BARBITURATES **Coverage for Medicare dual-eligible members**	Dual-eligible Medicare-Medicaid Beneficiaries: Beginning on January 1, 2013 Colorado Medicaid will no longer cover barbiturates for Medicare-Medicaid enrollees (dual-eligible members). For Medicaid primary members, barbiturates will be approved for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review	(3 months for neonatal narcotic abstinence syndrome)
BENLYSTA (belimumab)	**Benlysta** (belimumab) prior authorization may be approved only when documentation has been received indicating that the drug is being administered in the member's home or long-term care facility. The member must also meet the following criteria: • Member is age ≥ 5 years with active, autoantibody-positive systemic lupus erythematosus (SLE) and receiving standard therapy OR member is an adult with active lupus nephritis who are receiving standard therapy AND • Member has incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND • Member maintains standard therapy while on BENLYSTA (belimumab).	One year
BENZODIAZEPINES Dual-eligible Medicare-Medicaid Beneficiaries	Dual-eligible Medicare-Medicaid Beneficiaries: Benzodiazepines will no longer be a Medicaid benefit for Medicare-Medicaid enrollees (dual-eligible members). The claims are no longer excluded from Medicare part D coverage and therefore must be billed to Medicare part D. Colorado Medicaid will no longer cover these medications for these members beginning on January 1, 2013.	One year
BLOOD PRODUCTS	FDA approved indications if given in the member's home or in a long-term care facility: Plasma protein fraction; shock due to burns, trauma, surgery; hypoproteinemia; adult respiratory distress syndrome; cardiopulmonary bypass; liver failure; renal dialysis; or hemophilia.	Lifetime
BONE RESORPTION SUPPRESSION AND RELATED AGENTS (Injectable Formulations) Boniva, Aredia, Miacalcin, Zemplar, Hectorol, Zometa, Reclast, Pamidronate, Prolia, Ganite	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member's home. **Prolia** (denosumab) will be approved if the member Meets the following criteria: • Member is in a long term care facility or home health (this medication is required to be administered by a healthcare professional) AND • Member has one of the following diagnoses: o Postmenopausal osteoporosis with high fracture risk o Osteoporosis o Bone loss in men receiving androgen deprivation therapy in prostate cancer o Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer AND • Member has serum calcium greater than 8.5mg/dL AND	One year

	• Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND
	• Has trial and failure of preferred bisphosphonate for one year AND (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
	• Member meets ANY of the following criteria:
	  ○ has a history of an osteoporotic vertebral or hip fracture
	  ○ has a pre-treatment T-score of < -2.5
	  ○ has a pre-treatment T-score of < -1 but > -2.5 AND either of the following:
	  • Pre-treatment FRAX score of > 20% for any major fracture
	  • Pre-treatment FRAX score of > 3% for hip fracture
	
	Maximum dose of Prolia is 60mg every 6 months	

BOTULINUM TOXIN Botox, Dysport, Myobloc, Xeomin	Botulinium toxin agents may receive approval if meeting the following criteria: • Medication is being administered in a long-term care facility or the member's home by a healthcare professional AND • Member has a diagnosis of cervical or facial dystonia ***Not approved for Cosmetic Purposes***	One year
BOWEL PREPERATION AGENTS	For the following Bowel Preparation Agents, members will require a prior authorization for quantities exceeding 2 units in 30 days. • Colyte • Gavilyte-C • Gavilyte-H • Gavilyte-N • Gialax • Golytely® • Moviprep • Peg-Prep • Suprep • Sutab • Trilyte	30 days
BRAND FAVORED MEDICATIONS	See "Brand Favored Product List" on the Pharmacy Resources webpage at https://www.colorado.gov/pacific/hcpf/pharmacy-resources .	
BRONCHITOL (mannitol)	**Bronchitol** (mannitol) may be approved for members meeting the following criteria: • Bronchitol (mannitol) is being prescribed as an add-on therapy for cystic fibrosis (CF) AND • Member is an adult (≥ 18 years of age) with a confirmed diagnosis of cystic fibrosis AND • Member has severe lung disease as documented by bronchoscopy or CT scan AND • Member has an FEV1 between 40% and 89% of predicted value AND • Member is receiving other appropriate standard therapies for management of cystic fibrosis (such as inhaled antibiotic, airway clearance physiotherapy, inhaled beta2 receptor agonist) AND • Member has had an adequate trial and failure of nebulized hypertonic saline, or is currently using nebulized hypertonic saline on a regular basis AND • Member has trialed and failed twice-daily treatment with recombinant human deoxyribonuclease (dornase alfa, rhDNase). Failure is defined as allergy, intolerable side effects or inadequate response AND • Member has successfully passed the Bronchitol Tolerance Test (BTT) under the supervision of a healthcare practitioner AND	One year

	• Member has been prescribed a short-acting bronchodilator to use 5 to 15 minutes before each dose of Bronchitol (mannitol). Maximum dose: 400mg twice a day by oral inhalation Quantity limit: One 4-week Treatment Pack (4 inhalers, 560 capsules) per 28 days	
BUPRENORPHINE-CONTAINING PRODUCTS (used for opioid use disorder/opioid dependency*)	**Bunavail** (buprenorphine/naloxone) buccal film will be approved for members who meet all of the following criteria: • Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex® or Suboxone® AND • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has contraindication to generic buprenorphine/naloxone SL tablets or Suboxone® films. **Buprenorphine/Naloxone** sublingual film will be approved if the all of following criteria are met: • Effective 10/01/19: Brand Suboxone® sublingual film is covered as a favored product, and for members meeting all of the following criteria (or members with current prior authorization approval on file), claims for brand Suboxone® sublingual film will pay with submission of DAW code 0, 1, or 9. Prior authorization for generic buprenorphine/naloxone sublingual film will require prescriber verification that there is clinical necessity for use of the generic product in addition to meeting all of the following: o The prescriber is authorized to prescribe Suboxone AND o The member has an opioid dependency AND o The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids AND o Will not be approved for the treatment of pain AND o Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days AND o Will not be approved for more than 24mg of buprenorphine/day **Buprenorphine/Naloxone** sublingual tablet will be approved if all of the following criteria are met: • The prescriber is authorized to prescribe buprenorphine/naloxone AND • The member has an opioid dependency AND • The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids AND • Will not be approved for the treatment of pain AND • Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days AND • Will not be approved for more than 24mg of buprenorphine/day **Sublocade** (buprenorphine extended-release) injection will be approved for members who meet all of the following criteria:	One year

	• Sublocade is being administered in a long-term care facility or in a member's home by a home healthcare provider (all other claims must be submitted through the medical benefit) AND • Sublocade is being dispensed directly to the home healthcare professional (medication should not be dispensed directly to the member) AND • Provider attests to member's enrollment in a complete treatment program including counseling and psychosocial support AND • Member must have documented diagnosis of moderate to severe opioid use disorder AND • Member must have initiated therapy with a transmucosal buprenorphine-containing product, and had dose adjustment for a minimum of 7 days AND • Maximum dose is 300 mg injection every month **Suboxone** sublingual film (brand name) will be approved if all of the following criteria are met: • The prescriber is authorized to prescribe Suboxone AND • The member has an opioid dependency AND • The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids AND • Will not be approved for the treatment of pain AND • Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days AND • Will not be approved for more than 24mg of buprenorphine/day **Subutex** (buprenorphine) sublingual tablet will be approved if all of the following criteria are met: • The prescriber is authorized to prescribe Subutex AND • The member has an opioid dependency AND • The member is pregnant or the member is allergic to Naloxone AND • Subutex will not be approved for the treatment of pain AND • Subutex will not be approved for more than 24mg/day **Zubsolv** (buprenorphine/naloxone) sublingual tablet will be approved if all of the following criteria are met: • Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex or Suboxone AND • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films. **Buprenorphine products indicated for treating pain are located on the preferred drug list (PDL)*	
BYNFEZIA (octreotide acetate)	**Bynfezia** (octreotide acetate) may be approved if all of the following criteria are met: • Member is an adult (≥ 18 years of age) with a confirmed diagnosis of acromegaly OR severe diarrhea and flushing episodes associated with metastatic carcinoid tumors OR vasoactive intestinal peptide tumors (VIPomas) AND	One year

	• Bynfezia (octreotide acetate) is prescribed by, or in consultation with, an endocrinologist or oncologist AND • Member has trialed and failed octreotide acetate injection solution (vial). Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND • Provider confirms that member has had a baseline thyroid function test drawn prior to the initiation of Bynfezia (octreotide) and plans to monitor periodically during treatment AND • For treatment indication acromegaly, the following criteria are met: o The member has trialed and failed bromocriptine mesylate at maximally tolerated doses. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND o The member cannot be treated with surgical resection or pituitary irradiation Maximum Dose: • Acromegaly: 1500 mcg/day (doses > 300 mcg/day may not result in additional benefit) • Carcinoid Tumors: 750 mcg/day • VIPomas: 750 mcg/day (doses > 450 mcg/day are generally not required)	
CABLIVI (caplacizumab)	**Cablivi** (caplacizumab) may be approved if all the following criteria have been met: • Member is 18 years or older **AND** • Member has a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND** • Member is undergoing plasma exchange and is receiving immunosuppressive therapy **AND** • Cablivi (caplacizumab) is being prescribed by or in consultation with a hematologist **AND** • Prescriber is aware that concomitant use of CABLIVI with any anticoagulant or underlying coagulopathy may increase the risk of severe bleeding, including epistaxis and gingival hemorrhage **AND** • Member has not experienced more than 2 recurrences of aTTP while on Cablivi (caplacizumab) **AND** • To bill for Cablivi (caplacizumab) under the pharmacy benefit, the medication must be administered in the member's home or in a long-term care facility. Maximum dose: • First day of treatment: 11 mg prior to plasma exchange, followed by 11 mg after plasma exchange • Subsequent days during treatment period: 11 mg once daily	One year
CERDELGA (eliglustat)	**Cerdelga** (eliglustat) may be approved if all of the following criteria are met: • Member has a diagnosis of Gaucher disease type 1 **AND** • Documentation has been provided to the Department that the member is a CYP2D6 extensive, intermediate, or poor metabolizer as detected by an FDA cleared test **AND** • Members who are CYP2D6 intermediate or poor metabolizers are not taking a strong CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, nefazodone) **AND**	One year

	• Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g, sertraline, duloxetine, quinidine, paroxetine, fluoxetine, buproprion, terbinafine) **AND** a strong or moderate CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, fluconazole, nefazodone, verapamil, diltiazem) Quantity Limits: Max 60 tablets/30 days	
CHLOROQUINE	Effective 03/24/20: Prior authorization may be approved for FDA-labeled indication, dose, age, and role in therapy as outlined in product package labeling.	Chronic conditions: One year Acute conditions: Duration of acute use
CLIENT OVERUTILIZATION PROGRAM (COUP)	Effective 9/14/19, pharmacy claims for members enrolled in Health First Colorado's COUP (Client Overutilization Program) program may deny for these members when filling prescriptions at a pharmacy that is not their designated COUP lock-in pharmacy or filling a medication prescribed by a provider that is not their designated COUP lock-in prescriber. Health First Colorado Reginal Accountable Entity (RAE) organizations work with members enrolled in COUP to assist with coordinating care and improving services provided to these members. Members and providers should contact the member's RAE organization for questions regarding the COUP program.* Contact information for Health First Colorado RAE regions can be found at https://www.colorado.gov/pacific/hcpf/accphase2. Additional information regarding the COUP program and enrollment criteria can be accessed at https://www.colorado.gov/pacific/hcpf/client-overutilization-program. **For questions regarding pharmacy claims denials that are unable to be addressed during normal RAE organizational business hours (M-F 8:00 AM – 4:00 PM Mountain Standard Time), members and providers may contact the Magellan Helpdesk at 1-800-424-5725.*	
COUGH AND COLD (Prescription Products)	Effective 03/19/20*, select prescription cough and cold products are covered for members of all ages without prior authorization. Eligible products include: • Non-controlled prescription cough and cold medications • Prescription guaifenesin with codeine oral solution formulations Coverage of all other prescription cough and cold medications (not identified above) will be subject to meeting the following criteria: • For members < 21 years of age, no prior authorization is required OR • For members ≥ 21 years of age, prior authorization may be approved with diagnosis of a chronic condition (such as COPD or asthma). For members with dual Medicare eligibility, pharmacy claims for prescription cough and cold medications prescribed for chronic conditions should be billed to Medicare. Prescription cough and cold medications prescribed for dual Medicare eligible members for acute conditions are covered through the Health First Colorado pharmacy benefit with completion of prior authorization verifying use for acute illness. *Note: For OTC cough and cold product coverage, see "OTC Products" section.*	One year

	*Until such time changes are implemented in the claims system, pharmacies may call the Magellan helpdesk at 1-800-424-5725 for prior authorization overrides for eligible products.	
DARAPRIM (pyrimethamine)	**Daraprim** (pyrimethamine) may be approved if all the following criteria are met: • Member is being treated for toxoplasmic encephalitis or congenital toxoplasmosis or receiving prophylaxis for congenital toxoplasmosis AND • Daraprim is prescribed in conjunction with an infectious disease specialist AND • Member does not have megaloblastic anemia due to folate deficiency AND • For prophylaxis, member has experienced intolerance to prior treatment with trimethoprim-sulfamethoxazole (TMP-SMX) meeting one of the following: o Member has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate o Member has evidence of life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome) OR • Member is being treated for acute malaria due to susceptible strains of plasmodia AND • Member has tried and had an inadequate response or intolerant to two other malaria treatment regimens (such as but not limited to atovaquone/proguanil, Coartem, chloroquine, hydroxychloroquine, chloroquine plus Primaquine, quinine plus clindamycin, quinidine plus doxycycline) AND • Daraprim is prescribed in conjunction with an infectious disease specialist with travel/tropical medicine expertise AND • Member does not have megaloblastic anemia due to folate deficiency Note: The Center for Disease Control does not recommend Daraprim for the prevention or the treatment of malaria	8 weeks
DESI DRUGS	DESI drugs (Drugs designated by the Food and Drug Administration as Less Than Effective Drug Efficacy Study Implementation medications) are not a covered benefit.	
DIFICID (fidoxomicin)	**Dificid** (fidoxomicin) may be approved if all the following criteria are met: • Member is age ≥ 6 months **AND** • Member has a documented diagnosis (including any applicable labs and/or tests) for Clostridium difficile-associated diarrhea **AND** • Prescribed by or in conjunction with a gastroenterologist or an infectious disease specialist **AND** • Member has failed at least a 10 day treatment course of oral vancomycin. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **M**aximum quantity: 20 tablets per 30 days 136 mL per 10 days	1 month
DIHYDROERGOTAMINE PRODUCTS (Non-Oral)	**Migranal** and other non-oral dihydroergotamine product formulations may be approved if meeting ALL of the following criteria: • Member is not currently taking a potent CYP 3A4 inhibitor (for example, protease inhibitor, macrolide antibiotic) AND • Member does not have uncontrolled hypertension or ischemic heart disease AND • Product is being prescribed for cluster headache (vial only) or acute migraine treatment (vial and nasal spray) AND	One year

	• Non-oral dihydroergotamine product formulations (with exception of the generic vial) may be approved with adequate trial and failure of the generic dihydroergotamine vial. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. AND • If dihydroergotamine product is being prescribed for acute migraine treatment, member has adequate trial and/or failure of 2 triptan agents (for example sumatriptan, naratriptan)and 1 NSAID medication. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. OR • If dihydroergotamine product is being prescribed for cluster headaches, member has adequate trial and/or failure of 2 triptan agents. Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. <u>Grandfathering:</u> Members currently utilizing a non-oral dihydroergotamine product formulation (based on recent claims history) may receive one year approval to continue therapy with that medication. <u>Maximum Dosing:</u> Migranal (dihydroergotamine) spray: 16mg per 28 days Dihydroergotamine vial: 24mg per 28 days	
DOPTELET (avatrombopag)	**Doptelet** (avatrombopag) prior authorization may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a confirmed diagnosis of thrombocytopenia with chronic liver disease who is scheduled to undergo an elective procedure AND • Member has trial and failure of Mulpleta (lusutrombopag). Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions. • Quantity Limit: 5 day supply per procedure OR • Member is 18 years of age or older AND • Member has a documented diagnosis of chronic immune thrombocytopenia AND • Member has trial and failure of Promacta (eltrombopag). Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions. • Quantity Limit: 40mg daily	One year
DOXEPIN TOPICAL PRODUCTS	**Prudoxin** and generic doxepin 5% cream may be approved if the member meets the following criteria: • Member is 18 years of age or older AND • Member has a diagnosis of moderate pruritis with atopic dermatitis or lichen simplex chronicus AND	One year

	• Member has trial and failure‡ of one prescription-strength topical corticosteroid AND one topical immunomodulator product (see PDL for preferred products) **Zonalon** may be approved if member has trial and failed‡ either doxepin 5% cream or Prudoxin® and meets all of the following criteria. • Member has a diagnosis of moderate pruritis with atopic dermatitis or lichen simplex chronicus AND • Member has trial and failure‡ of one prescription-strength topical corticosteroid AND one topical immunomodulator product (see PDL for preferred products) <u>Quantity Limit for Topical Doxepin Products:</u> 8 days-supply per 30 day period ‡Failure is defined as: lack of efficacy of a three-month trial, allergy, intolerable side effects or significant drug-drug interaction	
DUPIXENT (dupilumab)	**Dupixent** (dupilumab) may be approved for members meeting the following criteria: <u>*Atopic Dermatitis:</u> • Member is 6 years of age or older AND • Member has a diagnosis of moderate to severe chronic atopic dermatitis AND • Member has baseline Investigator Global Assessment (IGA) score for atopic dermatitis severity of at least 3 (Scored 0-4, 4 being most severe) OR moderate erythema and moderate papulation/infiltration AND • Member has been educated by provider regarding the elimination of exacerbating factors including aeroallergens, food allergens, and contact allergens AND • Member has been educated by provider regarding the appropriate use of emollients and moisturizers for promotion of skin hydration AND • Member has trialed and failed‡ the following agents: o Two medium potency to very-high potency topical corticosteroids [such as mometasone furoate, betamethasone dipropionate, or fluocinonide (see PDL for list of preferred products)] AND o Two topical calcineurin inhibitors (see PDL for list of preferred products) AND • Must be prescribed by or in conjunction with a dermatologist, allergist/immunologist, or rheumatologist AND • Initial authorization will be for 18 weeks. Continuation will be authorized for 12 months with prescriber attestation to 16-week IGA score showing improvement by at least 2 points OR clinically significant improvement with Dupixent® regimen. <u>*Asthma:</u> • Member is 12 years of age or older AND • Member has a diagnosis of moderate to severe asthma (on medium to high dose inhaled corticosteroid and a long-acting beta agonist) with eosinophilic phenotype OR <u>oral</u> corticosteroid dependent asthma AND • Member has had at least one asthma exacerbation in the past year requiring systemic corticosteroids or emergency department visit or	Initial: See criteria Continued: One year

hospitalization OR dependence on daily oral corticosteroid therapy PLUS regular use of high dose inhaled corticosteroid PLUS an additional controller medication AND

- Medication is being prescribed as add-on therapy to existing regimen AND
- Medication is being prescribed by or in conjunction with a rheumatologist, allergist, or pulmonologist AND
- For indication of moderate to severe asthma with eosinophilic phenotype:
  - baseline lung function (FEV_1) is provided and baseline eosinophils are greater than 300 cells/mcL AND
  - Initial authorization will be for 12 weeks. Continued authorization will require prescriber attestation of improvement in FEV_1 of 25% from baseline and will be for 12 months
- For indication of oral corticosteroid dependent asthma:
  - Dosing of the oral corticosteroid is provided AND
  - Initial authorization will be 24 weeks. Continued authorization will require prescriber attestation of a reduction of oral corticosteroid by at least 50% and will be for 12 months

*Chronic Rhinosinusitis with Nasal Polyposis:

- If member has a diagnosis of asthma or atopic dermatitis, they must meet listed criteria for that indication
- Member is 18 years of age or older AND
- Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) AND
- Member has a baseline bilateral endoscopic nasal polyps score (NPS; scale 0-8) AND nasal congestion/obstruction score (NC; scale 0-3) averaged over 28-day period AND
- Member has trialed and failed‡ therapy with three intranasal corticosteroids (see PDL Class) AND
- Medication is being prescribed by or in conjunction with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist AND
- Dose of Dupixent (dupilumab) 300mg every 2 weeks is used AND
- Initial authorization will be for 24 weeks, for additional approval member must meet the following criteria:
  - NC and NPS scores are provided and show a 20% reduction in symptoms AND
  - Member continues to use primary therapies such as intranasal corticosteroids

Quantity Limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)

*For members that have a diagnosis of asthma and/or atopic dermatitis in addition to another indicated diagnosis for Dupixent (dupilumab), the member must meet criteria listed above for the respective diagnosis.

	‡Failure is defined as a lack of efficacy with one month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.	
EGRIFTA (tesamorelin acetate)	**Egrifta** or **Egrifta SV** will be approved if all the following criteria is met: • Must be prescribed in consultation with a physician who specializes in HIV/AIDS AND • Member is 18 years of age or older AND • Member has a diagnosis of HIV-related lipodystrophy with excess abdominal fat meeting the following criteria: o Male member must have a waist circumference of at least 95cm (37.4in) and a waist to hip ratio of at least 0.94 OR o Female member must have a waist circumference of at least 94cm (37in) and a waist to hip ratio of at least 0.88 AND o Baseline waist circumference and waist to hip ratio must be provided • Member is currently receiving highly active antiretroviral therapy including protease inhibitors, nucleoside reverse transcriptase inhibitor, or non-nucleoside reverse transcriptase inhibitors AND • Member does not have a diagnosis of hypophysectomy, hypopituitarism, pituitary surgery, head irradiation or head trauma AND • Member does not have any active malignancy or history of malignancy AND • For women of childbearing potential, member must have a negative pregnancy test within one month of therapy initiation	6 months
ELESTRIN GEL (estradiol)	A prior authorization will only be approved if a member has tried and failed on generic oral estradiol therapy and diagnosed with moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
EMFLAZA (deflazacort)	**Emflaza** (deflazacort) may be approved if all the following criteria are met: • Member is at least 2 years of age or older AND • Member has diagnosis of Duchenne muscular dystrophy and a documented mutation in the dystrophin gene AND • Member must have documented (per claims history or provider notes) adequate trial and/or failure to prednisone therapy, adequate trial duration is at least three month. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND • The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders. AND • Serum creatinine kinase activity at least 10 times the upper limit of normal at some stage in their illness AND • Absence of active infection including tuberculosis and hepatitis B virus Maximum dose: 0.9mg/kg daily for tablets and suspension (may be rounded up to nearest ml)	One year
EMPAVELI (pegcetacoplan)	**Empaveli** (pegcetacoplan) may be approved if all of the following criteria are met: • Member is 18 years of age or older AND • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional OR the member has received proper training for administration of subcutaneous infusion AND • Member is not pregnant AND • Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high-sensitivity flow cytometry AND • Member has received vaccination against encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of Empaveli therapy,	One year

	unless treatment cannot be delayed OR if the vaccines were administered within the last 2 weeks, member has received 2 weeks of antibacterial drug prophylaxis AND • Member does not have any active infections caused by encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type b) AND • Member has a baseline lactate dehydrogenase result available and is being monitored by prescriber AND • Empaveli is not being used in combination with Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), or other medications to treat PNH (with exception of combination used during interval for switching between products) AND • Empaveli is being prescribed by, or in consultation with, a hematologist, immunologist, or nephrologist AND • Prescriber is enrolled in the Empaveli Risk Evaluation and Mitigation Strategy (REMS) program. Maximum dose: 1,080 mg (1 single-dose vial) every three days	
EMVERM (mebendazole)	**Emverm** (mebendazole) will be approved for members that meet the following criteria: • Member is 2 years or older AND • Member has a diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworm), Ascariasis (roundworm), Enterobiasis (pinworm), or Trichuriasis (whipworm) AND • Member has failed a trial of albendazole for FDA approved indication and duration (Table 1) (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND • For diagnoses other than pinworm, Emverm is being prescribed by an infectious disease specialist AND • Female members have a negative pregnancy test AND • Emverm® Is being prescribed in accordance to FDA dosing and duration (Table 1) Quantity limits: Based on indication (Table 1)	See Table

	Table 1: Emverm FDA Approved Dosing and Duration in Adults and Children **Diagnosis** / **Dose** / **Duration** / **Quantity Limits** Ancylostoma duodenale or Necator americanus (hookworm) — 100 mg twice daily — 3 consecutive days, may be repeated in 3 weeks in needed. — 6 tablets/member Ascariasis (roundworm) — 100 mg twice daily — 3 consecutive days, may be repeated in 3 weeks if needed. — 6 tablets/member Enterobiasis (pinworm) — 100 mg once — May give second dose in three weeks if needed. — 2 tablets/member Trichuriasis (whipworm) — 100 mg twice daily — 3 consecutive days, may be repeated in 3 weeks in needed. — 6 tablets/member	

ENSPRYNG (satralizumab-mwge)	**Enspryng** (satralizumab-mwge) may be approved if meeting the following criteria:
	• Member is an adult (≥ 18 years of age) **AND**
	• Member has a documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) that includes a positive serologic test for anti-aquaporin-4 (AQP4) antibodies **AND**
	• Member has a past medical history of <u>at least one</u> of the following:
	  ○ Optic neuritis
	  ○ Acute myelitis
	  ○ Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
	  ○ Acute brainstem syndrome
	  ○ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
	  ○ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
	AND
	• Member does not have any active infections, including localized infections **AND**
	• Member does not have active Hepatitis B infection, as confirmed by negative surface antigen [HBsAg] and anti-HBV tests **AND**
	• Member does not have active or untreated latent tuberculosis **AND**
	• Provider confirms that member has a baseline Liver Function Panel drawn prior to initiation of ENGSPYNG treatment and member does not has an AST or ALT level greater than 1.5 times the upper limit of normal **AND**
	• Provider confirms that neutrophil counts will be checked 4 to 8 weeks after initiation of ENSPRYNG therapy, and thereafter at regular clinically determined intervals to monitor for decreased neutrophil counts **AND**
	• Provider has screened for immunizations the member is due to receive according to immunization guidelines **AND**
	• Any live or live-attenuated vaccines will be administered at least 4 weeks prior to initiation of ENSPRYNG **AND**
	• Any non-live vaccines will be administered at least 2 weeks prior to initiation of ENSPRYNG (whenever possible) **AND**
	• ENSPRYNG is prescribed by or in conjunction with a neurologist.
		Initial: 6 months
		
		Continued: One year

	Reauthorization: After receiving initial six month approval, EYNSPRYNG (satralizumab-mwge) may be approved for one year if the following criteria: • Member has shown no adverse effects to ENGSPYNG treatment at a maintenance dose of 120 mg subcutaneously every 4 weeks **AND** • Member does not have any active infections (including localized infections) **AND** • Member does not have an AST or ALT level greater than 1.5 times the upper limit of normal **AND** • Provider confirms that neutrophil counts are currently within normal limits and will continue to be monitored at clinically determined intervals during ENSPRYNG therapy. Maximum dose: 120 mg subcutaneously every 2 weeks for three doses, followed by 120 mg subcutaneously every 4 weeks maintenance dose.	
ERECTILE DYSFUNCTION OR SEXUAL DYSFUNCTION PRODUCTS Caverject, Cialis, Edex, Imvexxy, Levitra, Muse, Viagra, Addyi, Osphena, Premarin Cream, Sildenafil, Tadalafil (generic Cialis), Staxyn, Stendra, Xiaflex, Yohimbine	Medications prescribed for use for erectile dysfunction or other sexual dysfunction diagnoses are not covered (these medications may be eligible for approval only when prescribed for other FDA-labeled or medically accepted indications). **Yohimbine** prior authorization may be approved for use as a mydriatic agent or a vasodilator (not related to erectile dysfunction). Prior authorizations for use of yohimbine for erectile dysfunction will not be approved. **Sildenafil** prior authorization may be approved for off-label use for Raynaud's disease.	See criteria Do not qualify for emergency 3 day supply
ERGOMAR (ergotamine tartrate)	**Ergomar** (ergotamine tartrate) sublingual tablet may be approved for members meeting the following criteria: • Ergomar (ergotamine tartrate) is being prescribed to prevent or treat vascular headache (migraine, migraine variants or so-called "histaminic cephalalgia") AND • Member has a negative pregnancy test within 30 days of receipt of Ergomar AND • Member is not taking a potent CYP 3A4 inhibitor (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin and troleandomycin) AND • Member has adequate trial and/or failure of 2 triptan agents (see PDL class) AND • Member has adequate trial and/or failure of 2 NSAIDs (see PDL class) AND • Member has adequate trial and/or failure of dihydroergotamine vial. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. Maximum quantity: 20 tablets per 28 days (40mg per 28 days) *Note: Cafergot (ergotamine/caffeine) tablet is covered without prior authorization.*	One year
ESBRIET (pirenidone)	**Esbriet** (pirenidone) may be approved if the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND	One year

	• Member does not have severe (Child Pugh C) hepatic impairment, severe renal impairment (Crcl<30 ml/min), or end stage renal disease requiring dialysis AND • Female members of reproductive potential must have been counseled regarding risk to the fetus AND • Member is not receiving a strong CYP1A2 inducer (e.g, carbamazepine, phenytoin, rifampin)	
EUCRISA (crisaborole)	**Eucrisa** (crisaborole) may be approved if the following criteria are met: • Member is at least 3 months of age and older AND • Member has a diagnosis of mild to moderate atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to at least two medium- to high-potency topical corticosteroid for a minimum of 2 weeks, or is not a candidate for topical corticosteroids AND • Member must have trialed and/or failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. AND • Must be prescribed by or in conjunction with a dermatologist or allergist/immunologist.	One year
EVRYSDI (risdiplam)	**Evrysdi** (risdiplam) may be approved if the following criteria are met: • Member is between 2 months of age and 25 years old **AND** • Member has documented diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA) by genetic testing and SMN1 mutation (two or more SMN2 gene copies must be specified) **AND** • Treating and prescribing provider(s) is a neurologist or pediatrician experienced in treatment of SMA **AND** • The prescriber attests that the member will be assessed by <u>at least one</u> of the following exam scales at baseline and during subsequent office visits: o Hammersmith Infant Neurological Examination Module 2 (HINE2) o Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) o Hammersmith Functional Motor Scale Expanded (HFMSE) o Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) o Motor Function Measure (MFM-32) o Revised Upper Limb Module (RULM) **AND** • Prior to the start of EVRYSDI treatment, the provider attests that the member meets all of the following: o Female members of childbearing potential have a documented negative pregnancy test within 2 weeks of initiating EVRYSDI therapy **AND** o Female members of childbearing potential have been instructed to use effective contraception during treatment with EVRYSDI and for at least 1 month after discontinuing treatment **AND** o Male members have been advised prior to initiation of therapy that their fertility may be compromised while being treated with EVRYSDI **AND** o Baseline liver function panel has been drawn and does not indicate hepatic impairment (EVRYSDI is extensively metabolized by the liver) **AND** o Drug-drug interactions including (but not limited to) MATE substrates such as metformin, cimetidine, and acyclovir, have been screened for, addressed if needed, and will be continually monitored **AND** • The following criteria are met:	15 months

	○ The member is not on a treatment plan that includes concomitant or previous treatment with ZOLGENSMA (onasemnogene abeparvovec-xioi) **AND** ○ The member is not receiving concomitant treatment with SPINRAZA (nusinersen) **OR** the member was treated with SPINRAZA previously and had to discontinue use due to lack of efficacy, allergy, intolerable side effects, or a contraindication to receiving intrathecal injections **AND** ○ The member's weight is provided and meets recommended daily dosing: **Age and Body Weight** / **Recommended Daily Dosage** 2 months to less than 2 years of age: 0.2 mg/kg 2 years and older, weighing less than 20 kg: 0.25 mg/kg 2 years and older, weighing 20 kg or more: 5 mg **Reauthorization criteria:** After 15 months, members may receive approval to continue therapy if the following criteria are met: • The member has shown no adverse events to EVRYSDI treatment **AND** • The member has demonstrated response to treatment by showing significant clinical improvement or no decline documented using quantitative scores using the same exam scale(s) used prior to initiating EVRYSDI treatment (please see number 4 of initial authorization criteria). Improvement of SMA-related symptoms must be compared to the baseline assessment and motor function must be measured against the degenerative effects of SMA **AND** • The prescriber provides the following information: ○ A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the motor exam completes any follow-up exam(s) **AND** ○ A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment **AND** ○ The member does not have hepatic impairment **AND** ○ Member weight is provided and meets recommended daily dosing: **Age and Body Weight** / **Recommended Daily Dosage** 2 months to less than 2 years of age: 0.2 mg/kg 2 years and older, weighing less than 20 kg: 0.25 mg/kg 2 years and older, weighing 20 kg or more: 5 mg Maximum dose: 5mg/day Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.	
EXJADE (deferasirox)	Please see "Jadenu and Exjade"	
EXONDYS 51 (eteplirsen)	**Exondys 51** (eteplirsen) may be approved if the following criteria are met: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND	One year

	• Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND • Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 51 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. pediatric neurologist, cardiologist or pulmonary specialist) AND • The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more. Maximum Dose: 30 mg/kg per week	
FASENRA (benrelizumab)	**Fasenra** (benrelizumab) prior authorization may be approved for member's meeting all of the following criteria: • Fasenra® is being administered by a healthcare professional in the member's home or in a long-term care facility (all other claims are billed through the Health First Colorado medical benefit) AND • Member is 12 years of age or older AND • Member has diagnosis of severe asthma with eosinophilic phenotype AND • Member has eosinophil count of at least 300 cells/µl AND • Fasenra is being prescribed as add-on therapy (not monotherapy) AND • Member is taking a high dose inhaled corticosteroids and a long-acting beta agonist AND • Member has had at least 2 asthma exacerbations requiring systemic corticosteroid therapy in the past 12 months Maximum dose: 30mg subcutaneous injection every 4 weeks for 3 doses, then every 8 weeks thereafter	One year
FERRIPROX (deferiprone)	**Ferriprox** (deferiprone) may be approved if the following criteria are met: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Ferriprox (deferiprone) is being prescribed for one of the following indications: o Treatment of transfusion-related iron overload in patients with thalassemia syndromes OR o Treatment of transfusion-related iron overload in patients with sickle cell disease or other anemias AND • Member has an absolute neutrophil count > 1.5 x 109 AND • Member has failed or has had an inadequate response to Desferal (deferoxamine) AND Exjade (deferasirox) as defined by serum ferritin >2,500mcg/L before treatment with Ferriprox OR member has been intolerant to or experienced clinically significant adverse effects to Desferal (deferoxamine) or Exjade (deferasirox) such as evidence of cardiac iron overload or iron-induced cardiac dysfunction. Maximum dose: 99mg/kg/day	One year
FIRDAPSE (amifampridine)	**Firdapse** (amifampridine) may be approved for members meeting the following criteria:	One year

	• Member is an adult ≥ 18 years of age AND • Member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) Max Dose: 80mg daily	
FLUORIDE PRODUCTS	Prescription fluoride products: • Prescription fluoride products will be approved for members less than 21 years of age without a prior authorization. • For members 21 years of age or older approval will be granted if using well water or living in an under-fluoridated area designated by the CDC*. • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. OTC fluoride products: • The following OTC fluoride products are eligible for prior authorization approval for all members using well water or living in an under-fluoridated area designated by the CDC*: fluoride chewable tablets, ludent fluoride chewable tablets, sodium fluoride 0.5mg/mL drops • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. *Information and reports regarding water fluoridation can be found on the CDC website at: https://nccd.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Coloradateid=8&stateabbr=CO&reportLevel=2.	One year
FUZEON (enfuvirtide)	If administered in the physician's office or delivered to physician's office, physician must bill as a medical claim on the 1500 claim form **(no PA required).** If administered in the member's home or in a long-term care facility, a prior authorization is required and must meet the criteria below for approval. Based on clinical trial data, ENF should be used as part of an *optimized* background regimen for treatment-experienced members: • For treatment-experienced members with evidence of HIV-1 replication, treatment should include at least one antiretroviral agent with demonstrated HIV-1 susceptibility on the basis of genotypic/phenotypic *resistance* assays, and *two* "active" antiretroviral agents. ○ Members must have limited treatment options among currently commercially available agents. • Members must be 18 years of age or older with advanced HIV-1 infection, and not responding to approved antiretroviral therapy. • Members must have a CD4 lymphocyte count less than 100 cells/mm3 and a viral load greater than 10,000 copies/ml (measurement within the last 90 days). Past adherence must be demonstrated based on: • Attendance at scheduled appointments, and/or • Prior antiretroviral regimen adherence, and/or • Utilization data from pharmacy showing member's use of medications as prescribed • Ability to reconstitute and self-administer ENF therapy. At 24 weeks, members must experience at least ≥ 1 $\log_{10}$ decrease in HIV RNA or have HIV RNA below quantifiable limits to continue treatment with ENF. Members are not eligible if antiretroviral treatment-naive and/or infected with HIV-2.	Six months

	Pre-approval is necessary Practitioner must either be Board Certified in Infectious Disease, or be an HIV experienced practitioner. Verification must be produced with the prior approval documents. **These guidelines may be modified on the basis of other payer formularies and/or the emergence of new data.**	
GALAFOLD (migalastat hydrochloride)	**Galafold** (migalastat hydrochloride) prior authorization may be approved for members meeting the following criteria: ▪ Member is ≥ 12 years of age **AND** ▪ The medication is being prescribed by or in consultation with a neurologist **AND** ▪ Member has a confirmed diagnosis of Fabry's disease with an amenable galactose alpha gene (GLA) variant per in vitro assay data. (Amenable GLA variants are those determined by a clinical genetics professional as pathologic or likely pathologic) **AND** ▪ Member does not have severe renal impairment or end-stage renal disease requiring dialysis. Maximum dose: 123 mg once every other day	One year
GAMASTAN (immune globulin)	Prior authorization may be approved for FDA-labeled indication, dose, age, and role in therapy as outlined in package labeling.	One year
GATTEX (teduglutide)	**Gattex** (teduglitide) may be approved if all of the following criteria are met: • Member is one year of age or older AND • Member has documented short bowel syndrome AND • Member is dependent on parenteral nutrition for twelve consecutive months AND • The prescribing physician is a gastroenterologist AND • Medical necessity documentation has been received and approved by Colorado Medicaid clinical staff (please fax to 303-866-3590 attn: Clinical Pharmacy Staff) • The initial prior authorization will be limited to a two month supply.	Two months initially; may be approved by State for up to one year
GENERIC MANDATE	<u>Brand Name Medications and Generic Mandate:</u> • Brand name drug products that have a therapeutically equivalent generic drug product (as determined by the FDA) will require prior authorization for brand product coverage and will be covered without a prior authorization if meeting one of the following exceptions: o The brand name drug is prescribed for the treatment of (and the prescriber has indicated dispense as written on the brand name prescription): ▪ Biologically based mental illness defined in 10-16-104 (5.5) C.R.S. ▪ Cancer ▪ Epilepsy ▪ HIV/AIDS o The Department has determined that the brand name product is lower cost than the therapeutically equivalent generic • Prior authorization for use of a brand name drug product that has a therapeutically equivalent generic (and does not meet exceptions above) may also be approved if: o The prescriber is of the opinion that a transition to the generic equivalent of the brand name drug would be unacceptably disruptive to the patient's stabilized drug regimen o The patient is started on the generic equivalent drug but is unable to continue treatment on the generic drug as determined by the prescriber	

GIMOTI (metoclopramide)	**Gimoti** (metoclopramide) may be approved for members meeting the following criteria: • Member is an adult (≥ 18 years of age) AND • Member has a confirmed diagnosis of acute or recurrent diabetic gastroparesis AND • Member has failed an adequate trial of metoclopramide solution. Failure is defined as allergy to inactive ingredients, inability to administer the solution through an enteral route (such as nasogastric or percutaneous endoscopic gastrostomy routes), or intolerable side effects AND • Member does not have a history of tardive dyskinesia AND • Member has not been diagnosed with a parkinsonian syndrome (such as Parkinson's disease, progressive supranuclear palsy, multiple system atrophy, or corticobasal degeneration) AND • Member does not have moderate to severe liver disease (Child Pugh B or C) AND • Member does not have moderate or severe renal impairment (creatinine clearance less than 60 mL/min) AND • Member is not a known poor metabolizer of CYP2D6, which may contribute to a higher potential for metoclopramide toxicity, including dystonias AND • For members ≥ 65 years of age, the following additional criteria are met: o Gimoti (metoclopramide) is not being prescribed as initial therapy for diabetic gastroparesis AND o Member has been stabilized on treatment with an oral metoclopramide dose of 10mg four times a day for at least 30 days prior to switching to Gimoti (metoclopramide) AND o Prescriber acknowledges that exceeding 12 weeks of <u>total</u> metoclopramide therapy (from all dosage forms and routes of administration) should be avoided in members who are ≥ 65 years of age due to risk of developing tardive dyskinesia. Maximum dose: One spray (15 mg) four times daily Duration limit (for members ≥ 65 years of age): Limited to 12-week supply per year	One year
GLYCATE (glycopyrollate)	**Glycate** (glycopyrollate) may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a diagnosis of peptic ulcer disease AND • Member <u>does not</u> have any of the following conditions: o Glaucoma o Obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy) o Obstructive disease of the gastrointestinal tract (such as achalasia, pyloroduodenal stenosis, etc.) o Paralytic ileus o Intestinal atony of the elderly or debilitated patient o Unstable cardiovascular status in acute hemorrhage o Severe ulcerative colitis o Toxic megacolon complicating ulcerative colitis o Myasthenia gravis AND	One year

	• Member has tried and failed at least two proton pump inhibitors (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND • Glycate (glycopyrrolate) is being used as adjunctive therapy AND • Glycate (glycopyrrolate) is being prescribed by or in consultation by a gastroenterologist	
HEMADY (dexamethasone)	**Hemady** (dexamethasone) may be approved for members meeting the following criteria: • Member is an adult (≥18 years of age) AND • Member has a confirmed diagnosis of multiple myeloma (MM) AND • Hemady (dexamethasone) is being prescribed in combination with other anti-myeloma treatment agents AND • Member does not have pheochromocytoma AND • Members of childbearing potential have been advised to use effective contraception during treatment and for at least one month after the last dose AND • Member has trialed and failed generic dexamethasone tablets. Failure is defined as allergy or intolerable side effects. Maximum dose: 40 mg/day	One year
HETLIOZ (tasimelteon)	**Hetlioz** (tasimelteon) may be approved for members meeting the following criteria: • Have a documented diagnosis of non-24-hour sleep wake disorder (non-24 or N24) by a sleep specialist AND • Member is completely blind	One year
HIGH COST CLAIMS	Pharmacy claims exceeding $19,999.00 may be approved following pharmacist review if the product meets current criteria (on the PDL/Appendix P when listed) OR if not listed, must meet the following per FDA product package labeling: • Diagnosis for labeled indication AND • Based on prescribed indication, prescription meets the following per label: o Dosing o Strength o Dosage form o Quantity o Days Supply AND • If product is an IV formulation or product labeling indicates that the medication should be administered by a healthcare professional, must meet approval criteria for physician administered drugs (see "Physician Administered Drugs" section).	
Homozygous Familial Hypercholesterolemia (HoFH)	**Juxtapid** (lomitapide) may be approved if all of the following criteria are met: • Member is 18 years of age or older; • Member has documented diagnosis of homozygous familial hypercholesterolemia (HoFH); • Member has failed therapy with high dose statin therapy (e.g. atorvastatin 40mg or higher, Crestor 20mg or higher) • The prescribing physician is enrolled in the Juxtapid REMS program. **Kynamro** (mipomersen) may be approved for members meeting all of the following criteria: • Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by either a or b	One year

	a. Laboratory tests confirming diagnosis of HoFH: LDLR DNA Sequence Analysis OR LDLR Deletion/Duplication Analysis for large gene rearrangement testing---only if the Sequence Analysis is negative OR APOB and dPCSK9 testing if both of the above tests are negative but a strong clinical picture exists. b. Documentation is received confirming a clinical or laboratory diagnosis of HoFH • Has a history of therapeutic failure, contraindication, or intolerance to high dose statin therapy or cholesterol absorption inhibitor (ezetimibe or bile acid resin) AND • Is being prescribed by a physician specializing in metabolic lipid disorders AND • The prescriber is enrolled in the REMS program AND • Is not being used as monotherapy AND • Has baseline liver function (AST, ALT, ALK, and total bilirubin) AND • Does not have moderate or severe hepatic impairment or active liver disease.	
HORMONE THERAPY	**Depo Provera (medroxyprogesterone)/ Lunelle (estradiol cipionate/ medroxyprogesterone)** FDA approved indication if given in a long-term care facility or in the members home: • Females: Contraception, uterine bleeding, amenorrhea, endometrial cancer • Males: Sexual aggression / Pedophilia – Only Depo-Provera will be approved • Not approved for administration in the physician's office – these must be billed through medical. **Implanon (etonogestrel)** See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center. **Nexplanon (etonogestrel)** • See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.	One year
HP ACTHAR (corticotropin)	**HP Acthar** (corticotropin) may be approved for members that meet the following criteria: • Member has a diagnosis of Infantile Spasms (West Syndrome) and meets <u>all</u> the criteria below: o Member is < 2 years of age o Member has electroencephalogram documenting diagnosis o Acthar is being used as monotherapy o Member does not have suspected congenital infection o Prescribed by or in consultation with a neurologist or epileptologist **OR** • Member has diagnosis of multiple sclerosis and is experiencing an acute exacerbation **AND** • Member does not have concomitant primary adrenocortical insufficiency or adrenocortical hyperfunction **AND** • Member has trialed and failed corticosteroid therapy prescribed to treat acute exacerbation due to multiple sclerosis. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Member is not receiving concomitant live or live attenuated vaccines **AND** • Member does not have one of the following concomitant diagnoses: o Scleroderma, osteoporosis, systemic fungal infections, ocular, herpes simplex, recent surgery, history of peptic ulcer disease, heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. **AND**	4 week supply

<table>
<tr>
<td></td>
<td>
HP Acthar will be approved based on the following FDA recommended doses. (see Table 1)
Table 1. FDA Recommended Dosing for HP Acthar
<table>
<tr><th>Diagnosis</th><th>Dose</th></tr>
<tr><td>Infantile Spasms under Age of 2 years</td><td>75 units/m^2 IM twice daily for two weeks; After two weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 units/m^2 IM in the morning for 3 days; 10 units/m^2 IM in the morning for 3 days; and 10 units/m^2 IM every other morning for 6 days (3 doses).</td></tr>
<tr><td>Acute Exacerbation of Multiple Sclerosis</td><td>80-120 units IM or SQ daily for 2-3 weeks</td></tr>
</table>
Quantity Limits: 4 week supply
</td>
<td></td>
</tr>
<tr>
<td>HUNTINGTON’S CHOREA / TARDIVE DYSKINESIA AGENTS</td>
<td>
Austedo (deutetrabenazine) may be approved if all the following criteria have been met:

Member is 18 years and older with chorea secondary to Huntington’s Disease OR Tardive Dyskinesia AND

For chorea secondary to Huntington’s Disease: member must have trialed and/or failed tetrabenazine, adequate trial duration is 1 month (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) OR
For tardive dyskinesia a baseline AIMS AND 12 week AIMS are required. If the 12 week AIMS does not show improvement from baseline, the prior authorization will no longer be approved

Member does not have untreated depression, suicidal thoughts, or a history of suicide attempt AND
Member has been informed of the risks of depression and suicidality AND
Member does not have severe hepatic impairment.

Maximum dose: 48mg/day
Quantity limit: 120 tablets 30 days

Xenazine (tetrabenazine) may be approved if all the following criteria have been met:

Member is 18 years and older with chorea secondary to Huntington’s Disease AND
Member does not have a history of suicide or untreated depression AND
Member has been informed of the risks of depression and suicidality AND
Member does not have severe hepatic impairment.

Maximum dose 50mg/day
Quantity limit: 60 tablets per 30 days

Ingrezza (valbenazine) may be approved if all the following criteria have been met:

Member is 18 years or older AND
Member has been diagnosed with tardive dyskinesia clinically AND
Has a baseline Abnormal Involuntary Movement Scale (AIMS) AND

</td>
<td>One year unless AIMS follow-up required</td>
</tr>
</table>

	• If there is no improvement at 6 weeks of therapy per AIMS, the medication will be discontinued. Quantity limits: • 40mg: 1.767 capsules/day • 60mg: 1 capsule/day • 80mg: 1 capsule/day Maximum dose: 80 mg/day	
HYDROXYCHLOROQUINE	Effective 03/24/20: Prior authorization may be approved for FDA-labeled indication, dose, age, and role in therapy as outlined in product package labeling.	Chronic conditions: One year Acute conditions: Duration of acute use

ILUMYA (tildrakizumab-asmn)	**Ilumya** (tildrakizumab-asmn) prior authorization may be approved for members meeting all of the following criteria:
	• Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
	• Member is 18 years of age or older and has diagnosis of moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy AND
	• Member does not have guttate, erythrodermic, or pustular psoriasis AND
	• Provider attests to:
	  • Baseline Provider Global Assessment (PGA) score for plaque psoriasis severity of at least 3 (Scored 0-4, 4 being most severe) OR
	  • Baseline Psoriasis Area and Severity Index (PASI) score of 12 or greater
	AND
	• Medication is being prescribed by or in conjunction with a rheumatologist, allergist, or dermatologist AND
	• Member has tried and failed‡ ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication AND
	• Initial authorization will be for 12 weeks Continued authorization for 12 months will require prescriber attestation to PGA score reduction of 2 or more points OR PASI score reduction of 75% OR prescriber attestation to clinically meaningful improvement with Ilumya® regimen.
	
	Claims for medications administered in a clinic or medical office are billed through the Health First Colorado medical benefit.
		Initial: 12 weeks
		
		Continued: One year

IVERMECTIN	Effective 09/14/21: Prior authorization may be approved for use for treating parasitic infections.	One year
JADENU and EXJADE (deferasirox)	**Jadenu** (deferasirox) or **Exjade** (deferasirox) may be approved for members that meet the following criteria: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Member has a diagnosis for chronic iron overload due to blood transfusion AND • Member is 2 years of age or older AND • Member has consistently high serum ferritin levels > 1000 mcg/L (demonstrated by at least 2 values in the prior three months OR	One year

	• Member has a diagnosis for chronic iron overload due to non-transfusion dependent thalassemia syndromes AND • Member is 10 years of age or older AND • Member has liver iron levels > 5 mg iron per gram of dry weight and serum ferritin levels > 300 mcg/L document in the prior three months Members must also meet the following additional criteria for all Jadenu and Exjade approvals: • Member does not have advanced malignancies and/or high-risk myelodysplastic syndromes AND • Member has a creatinine clearance > 40 ml/min AND • Member has a platelet count > 50 x 10^9/L <u>Maximum Dosing:</u> Maximum dose of Jadenu (deferasirox): 28mg/kg/day Maximum dose of Exjade (deferasirox): 40mg/kg/day	
JYNARQUE (tolvaptan)	**Jynarque** (tolvaptan) may be approved if the following criteria are met: • Member is an adult (≥ 18 years of age) AND • Member has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and is at risk for rapid disease progression AND • Medication is being prescribed by a nephrologist AND • Member does not have a history or sign/symptoms of significant liver impairment or injury (uncomplicated polycystic liver disease is not a contraindication for therapy) AND • Member is not taking a strong Cytochrome 3A inhibitor (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan, delavirdine and milk thistle) AND • Member is not using desmopressin (dDAVP) AND • If member is taking a moderate Cytochrome 3A inhibitor (such as erythromycin, fluconazole, or verapamil) JYNARQUE (tolvaptan) will be prescribed at a reduced dose AND • Member has normal blood sodium concentrations, is able to sense or respond to thirst, and has a normal blood volume AND • Member does not have urinary outflow obstruction or anuria <u>Maximum Dosing</u>: 120mg per day	One year
KALYDECO (ivacaftor)	**Kalydeco** (ivacaftor) may be approved if all of the following criteria are met: • Member has been diagnosed with cystic fibrosis AND • Member is an adult or pediatric patient 4 months of age or older AND • Documentation has been provided to indicate one of the following gene mutation: in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, R117H, S549R or another FDA approved gene mutation.* AND • Documentation has been provided that baseline ALT and AST have been accessed and are within 2x normal limits (AST and ALT should be examined every 3 months for the first year and annually after that).	One year

	* If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. Kalydeco® will only be approved at doses no more than 150 mg twice daily. Prior Authorizations need to be obtained yearly. Kalydeco® will not be approved for members who are concurrently receiving rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's Wort.	
KUVAN (sapropterin dihydrochloride)	**Kuvan** (sapropterin dihydrochloride) may be approved if all the following criteria are met: • Member is > 1 month old AND • Member has been diagnosed with hyperphenylalaninemia due to tetrahydrobiopterin responsive phenylketonuria AND • Prescriber is a metabolic specialist AND • Phenylalanine levels must be greater than 6 mg/dL for neonates through 12 years of age OR • Phenylalanine levels must be greater than 10 mg/dL for members between 13 to 17 OR • Phenylalanine levels must be greater than 15 mg/dL for members 18 years and older AND • Must be in conjunction with dietary restriction of phenylalanine • Initial approval will be for 1 month. Authorization may be extended if: o Members on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These members will be approved for another 1 month trial at the higher dose. o Members on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment will be discontinued. o Members responding to therapy receive additional authorization at 1-year intervals.	Initial approval one month
LAMPIT (nifurtimox)	**Lampit** (nifurtimox) may be approved if the following criteria are met: • Lampit (nifurtimox) is prescribed by or in conjunction with an infectious disease specialist, cardiologist or gastroenterologist AND • The member's age falls between term newborn and < 18 years of age AND • The member's weight is provided and is at least 2.5 kg (5.5 pounds) AND • The member has a diagnosis, documented and confirmed by blood smear, of Chagas disease (American Trypanosomiasis) caused by *Trypanosoma cruzi* AND • For pediatric members 2 to 12 years of age, the member has trialed and failed treatment with benznidazole. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND • For female members of childbearing potential, a documented negative pregnancy test is obtained within 2 weeks of initiating therapy AND • The member has received counseling (when appropriate) to not consume alcohol during treatment with Lampit (nifurtimox) AND • The prescription meets the following recommended daily dosing:	One year

	Lampit (nifurtimox) Dosing in Pediatric Patients Body weight group: Total daily dose 40 kg or greater: 8 to 10 mg/kg Less than 40 kg: 10 to 20 mg/kg Maximum Dosing: 300mg three times a day (900mg/day) for 60 days	
LHRH/GnRH Luteinizing Hormone Releasing Hormone/Gonadotropin Releasing Hormone	All claims for medications administered in a hospital, clinic, or physician's office are to be billed through the medical benefit. Claims billed through the pharmacy benefit may only receive approval if the medication is being administered in the member's home by a home health agency/provider or administered in a long-term care facility (see "Physician Administered Drugs" section). Prior authorization may be approved for FDA-labeled indications only. • **Eligard** (leuprolide): Palliative treatment of advanced prostate cancer • **Fensolvi** (leuprolide acetate): Central precocious puberty • **Lupaneta Pack** (leuprolide and norethindrone): Endometriosis • **Lupron** (leuprolide): Prostate cancer, endometriosis, uterine leiomyomata (fibroids), precocious puberty. Lupron may be approved for gender dysphoria based on the following criteria: o The member has a diagnosis of gender dysphoria which is made by a mental health professional with experience in treating gender dysphoria. Where available, the mental health professional should ideally have training in child and adolescent developmental psychology AND o The member should have at least 6 months of counseling and psychometric testing for gender identity prior to initiation of Lupron AND o The prescribing provider has training in puberty suppression using a gonadotropin releasing hormone agonist AND o Lupron may not be started until girls and boys exhibit physical changes of puberty (confirmed by levels of estradiol and testosterone, respectively) and no earlier than Tanner stages 2-3 (bilateral breast budding or doubling to tripling testicular size to 4-8 cc). o Duration of treatment: Lupron will be covered to a maximum of 16 years of age for gender dysphoria. • **Synarel** (nafarelin): Endometriosis, precocious puberty • **Trelstar** (triptorelin): Palliative treatment of advanced prostate cancer • **Triptodur** (triptorelin): Palliative treatment of advanced prostate cancer, precocious puberty	One year
LIPIDS/AMINO ACIDS/PLASMA PROTEINS	Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
LUCEMYRA (lofexidine)	**Lucemyra** (lofexidine) may receive prior authorization approval for members meeting all of the following criteria: • Member is 18 years of age or older **AND** • Lucemyra® is prescribed for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation **AND** • Member is not pregnant or nursing **AND**	14 days

	• Member is not experiencing withdrawal symptoms from substances other than opioids **AND**
	• Member is not currently taking monoamine oxidase inhibitors or allergic to imidazole drugs **AND**
	• Member does not have an abnormal cardiovascular exam prior to treatment:
	  o Clinically significant abnormal ECG (e.g., second or third degree heart block, uncontrolled arrhythmia, or QTc interval > 450 msec for males, and > 470 msec for females)
	  o Heart rate less than 45 bpm or symptomatic bradycardia
	  o Systolic blood pressure < 90 mm Hg or symptomatic hypotension (diastolic blood pressure < 60 mm Hg)
	  o Blood pressure > 160/100 mm Hg
	  o Prior history of myocardial infarction **AND**
	• Member has two-day trial and failed clonidine IR for opioid withdrawal symptoms. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
	
	Approval for Lucemyra (lofexidine) will be 14 days	

LUMIZYME (alglucosidase alfa)	**Lumizyme** (alglucosidase alfa) may be approved for members meeting all of the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member has diagnosis of Pompe disease (acid α-glucosidase [GAA] deficiency). Maximum dose: Lumizyme 20mg/kg every 2 weeks (IV Infusion)	One year
MAKENA (hydroxyprogesterone caproate)	**Makena** (hydroxyprogesterone caproate) may be approved for members that meet the following criteria: • The drug is being administered in the home or in long-term care setting • Member has a Singleton pregnancy and a history of singleton spontaneous preterm birth • Therapy is being initiated between 16 weeks gestation and 20 weeks 6 days gestation and continued through 36 weeks 6 days gestation or delivery (whichever occurs first) • Dose is administered by a healthcare professional. <u>Maximum Dosing:</u> Makena vial: 250mg IM once weekly Makena autoinjector: 275mg SubQ once weekly	See criteria
MALARIA PROPHYLAXIS EXCEEDING THIRTY DAYS	Prior authorization is required for claims exceeding a 30-day supply for medications used for malaria prophylaxis (e.g. atovaquone/proguanil, chloroquine, doxycycline, mefloquine, primaquine, tafenoquine) and may be approved for members meeting the following: • Prescriber verification that the member is traveling to a malaria endemic area for a period of time that requires duration of therapy exceeding thirty days. • Prescriber verification of member's duration of stay in the malaria endemic area and the total days needed for the malaria prophylaxis medication regimen. *Note: The Centers for Disease Control and Prevention recommendations for malaria prophylaxis therapy based on country of travel are available at www.cdc.gov*	See criteria

MIFEPRISTONE and MISOPROSTOL	**Mifeprex** (mifepristone) is excluded from coverage under the pharmacy benefit. **Korlym** (mifepristone) – Prior authorization may be approved for members meeting the following: • Mifepristone is not being prescribed for use related to termination of pregnancy AND • Mifepristone is being prescribed for use for hyperglycemia secondary to hypercortisolism in adult patients with Cushing's Syndrome who have type 2 diabetes or glucose intolerance and have failed or are not candidates for surgery. **Cytotec** (misoprostol) – *(Effective 07/18/19)* Prior authorization may be approved for members meeting the following: • Misoprostol is not being prescribed for use related to termination of pregnancy AND • Misoprostol is being prescribed for use as prophylaxis for reducing risk of NSAID-induced gastric ulcers in patients at high risk of complications from gastric ulceration OR is being prescribed for use for off-label indications supported by clinical compendia and peer-reviewed medical literature. *Note: See PDL for coverage information for misoprostol/NSAID combination products.*	One year
MIGERGOT (ergotamine/caffeine)	**Migergot** (ergotamine/caffeine) suppository may be approved for members meeting the following criteria: • Migergot (ergotamine/caffeine) suppository is being prescribed to prevent or treat vascular headache (migraine, migraine variants or so-called "histaminic cephalalgia") AND • Member has a negative pregnancy test within 30 days of receipt of Ergomar AND • Member is not taking a potent CYP 3A4 inhibitor (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin and troleandomycin) AND • Member has adequate trial and/or failure of 2 triptan agents (see PDL class) AND • Member has adequate trial and/or failure of 2 NSAIDs (see PDL class) AND • Member has adequate trial and/or failure of dihydroergotamine vial. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. Maximum quantity: 20 suppositories per 28 days *Note: Cafergot (ergotamine/caffeine) tablet is covered without prior authorization.*	One year
MOXATAG (amoxicillin)	A prior authorization will only be approved if a member has an allergic/intolerance to inactive ingredients in immediate release amoxicillin.	One year
MULPLETA (lusutrombopag)	**Mulpleta** (lusutrombopag) prior authorization may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a confirmed diagnosis of thrombocytopenia with chronic liver disease who is scheduled to undergo an elective procedure AND • Member has trialed and failed both dexamethasone and methylprednisolone (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions) AND	One year

	• Mulpleta is being prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist AND • Member has a baseline platelet count no more than 2 days before procedure. AND • Mulpleta (lusutrombopag) will not be administered with a thrombopoietic agent or spleen tyrosine kinase inhibitor (such as Promacta (eltrombopag), Nplate (romiplostim), or Tavalisse (fotamatinib) Quantity limit: 7 day supply per procedure	
MYALEPT (metreleptin)	**Myalept** (metreleptin) may be approved if all of the following criteria are met: • Prescriber is an endocrinologist who is enrolled in the Myalept REMS program AND • Member has a diagnosis of congenital or acquired generalized lipodystrophy AND • Member does not have HIV-related lipodystrophy AND • Member has a diagnosis of leptin deficiency AND • Member has been diagnosed with poorly controlled diabetes (HgA1c > 7) and/or hypertriglyceridemia (> 500 mg/dl) AND • Member has tried and failed two standard therapies for diabetes and/or hypertriglyceridemia	Six Months
MYCAPSSA (octreotide)	**Mycapssa** (octreotide) may be approved for members meeting the following criteria: • Member is an adult (≥ 18 years of age) with a confirmed diagnosis of acromegaly AND • Member has trialed and failed‡ treatment with bromocriptine mesylate at maximally tolerated doses AND • Member has responded to and tolerated 3 months of treatment with octreotide acetate injection (vial) OR lanreotide acetate injection AND • Member cannot be treated with surgical resection or pituitary irradiation AND • Member is not hypersensitive to octreotide of any components of Mycapssa (octreotide) capsules, which include but are not limited to gelatin, propylene glycol and povidone AND • Mycapssa (octreotide) is prescribed by, or in consultation with, an endocrinologist AND • Provider attests that insulin-like growth factor 1 (IGF-1) levels will be monitored every two weeks, along with member's signs and symptoms, during the dose titration period or as indicated, and that the Mycapssa (octreotide) dose will be adjusted based on these findings AND • Provider attests that blood glucose will monitored during initiation of treatment with Mycapssa (octreotide), and that blood glucose, thyroid function, and vitamin B12 levels will be monitored periodically during treatment AND • Provider confirms awareness of the potential for significant drug interactions between Mycapssa (octreotide) and other medications, including (but not limited to) cyclosporine, digoxin, lisinopril, oral contraceptives containing levonorgestrel, bromocriptine, beta blockers, and calcium channel blockers. Maximum Dose: 80 mg daily ‡Failure is defined as lack of efficacy with a 3-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.	One year

MYFEMBREE (relugolix, estradiol hemihydrate, norethindrone acetate)	**Myfembree** (relugolix, estradiol hemihydrate, norethindrone acetate) may be approved if meeting the following criteria: 1. Member is 18 years of age or older AND 2. Member is pre-menopausal AND 3. Member has a confirmed diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) AND 4. Member has tried and failed treatment with an estrogen-progestin contraceptive (oral tablets, vaginal ring, transdermal patch) OR a progestin releasing intrauterine device (IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy AND 5. The medication is prescribed by or in consultation with an obstetrician/gynecologist AND 6. Member does not have a high risk of arterial, venous thrombotic, or thromboembolic disorder, including: a. Women over 35 years of age who smoke OR b. Women with a past or current history of the following: i. DVT, PE, or vascular disease (such as cerebrovascular disease, coronary artery disease, peripheral vascular disease) OR ii. Thrombogenic valvular or thrombogenic rhythm diseases of the heart (such as subacute bacterial endocarditis with valvular disease, or atrial fibrillation) OR iii. Inherited or acquired hypercoagulopathies OR iv. Uncontrolled hypertension OR v. Headaches with focal neurological symptoms OR migraine headaches with aura if over age 35 AND 7. Member is not pregnant or breastfeeding AND 8. Member does not have known osteoporosis AND 9. Member does not currently have, or have a history of, breast cancer or other hormonally-sensitive malignancies AND 10. Member does not have known liver impairment or disease AND 11. Member will not receive Myfembree in combination with any medication that is contraindicated or not recommended per FDA labeling AND 12. Member has not previously received treatment with Orilissa (elagolix) 150 mg or Oriahnn (elagolix/estradiol/norethindrone acetate) for more than 24 months, or previous treatment with Orilissa (elagolix) 200 mg for more than 6 months AND 13. Member has been counseled that that Myfembree does not prevent pregnancy AND 14. Member has been instructed that only non-hormonal contraceptives should be used during Myfembree therapy and for at least 1 week following discontinuation AND 15. Prescriber acknowledges that assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter, and discontinuation of Myfembree should be considered if the risk associated with bone loss exceeds the potential benefit of treatment. Reauthorization: Members with a current 6-month prior authorization approval on file may receive an additional 6-month approval to continue therapy. Prior authorization requests for Myfembree will take into account exposure to all GnRH receptor antagonist medications (such as elagolix and relugolix) and will not be approved for a total exposure that exceeds 24 months.	6 months

	Maximum dose: 1 tablet daily (relugolix 40 mg, estradiol 1 mg, norethindrone acetate 0.5 mg)	
NAGLAZYME (galsulfase)	**Naglazyme** (galsulfase) may be approved for members meeting the following criteria: • Naglazyme (galsulfase) is being administered in a long-term care facility or in a member's home by a healthcare professional AND • Member is 5 years of age or older AND • Member has a confirmed diagnosis of Mucopolysaccharidosis, Type VI confirmed by the following: o Detection of pathogenic mutations in the ARSB gene by molecular genetic testing OR o Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes AND o Member has normal enzyme activity of a different sulfatase (excluding members with Multiple Sulfatase Deficiency) AND o Member has an elevated urinary glycosaminoglycan (uGAG) level above the upper limit of normal as defined by the reference laboratory AND • Member has a documented baseline 12-minute walk test (12-MWT), 3-minute stair climb test, and/or pulmonary function tests (such as FEV1) AND • Member has a documented baseline value for uGAG AND • Naglazyme (galsulfase) is being prescribed by or in consultation with a provider who specializes in inherited metabolic disorders Reauthorization Criteria: After one year, member may receive approval to continue therapy if meeting the following: • Has documented reduction in uGAG levels AND • Has demonstrated stability or improvement in one of the following: o 12-minute walk test OR o 3-minute stair climb test OR o Pulmonary function testing (such as FEV1) Max dose: 1 mg/kg as a 4-hour infusion weekly	One year
NALOXONE and **NALTREXONE**	**Narcan** (naloxone) intranasal does not require prior authorization. **Revia** (naltrexone) tablet does not require prior authorization. **Naloxone** vial/prefilled syringe: • does not require prior authorization. • The atomizer device for use with naloxone can be obtained by the pharmacy billing as a DME claim code A4210. The unit limit is 1 atomizer per vial/syringe dispensed up to a total of 15 per year. A prior authorization is not required. **Vivitrol** (naltrexone ER) injection: • Prior authorization for claims submitted under the pharmacy benefit may be approved when Vivitrol is administered by a healthcare professional in the member's home or in a long-term care facility. All other Vivitrol claims must be billed through the medical benefit. • Effective 01/01/2019, pharmacies that have entered into a collaborative practice agreement with one or more physicians for administration of Vivitrol may receive reimbursement for enrolled pharmacists to administer Vivitrol with appropriate claim submission through the Health First Colorado medical benefit	

	(claims for pharmacist administration of Vivitrol are not covered under the pharmacy benefit). Additional information regarding pharmacist enrollment and medical claims billing can be found at https://www.colorado.gov/hcpf/otc-immunizations . **Evzio** (naloxone) autoinjector – Product is not Medicaid rebate eligible per current status in Medicaid Drug Rebate Program (MDRP); product excluded *For buprenorphine/naloxone products, see "Buprenorphine-containing Products" section	
NAYZILAM (midazolam)	**Nayzilam** (midazolam) may be approved for members meeting the following criteria: • Member is 12 years of age or older AND • Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern and medical records are provided supporting this diagnosis AND • Member is stable on regimen of antiepileptic medications AND • Medication is being prescribed by or in conjunction with the same provider/provider team who manages the member's anti-epileptic regimen AND • Member is educated on appropriate identification of seizure cluster and Nayzilam (midazolam) administration not exceeding 2 doses per seizure cluster. Maximum dose: 4 nasal spray units per year unless used / damaged / lost Members are limited to one prior authorization approval on file for Valtoco (diazepam) and Nayzilam (midazolam). Grandfathering: If member is currently receiving Nayzilam (midazolam) intranasal, they may receive prior authorization approval to continue.	One Year
NEWLY APPROVED PRODUCTS AND CHANGE IN PRODUCT PRIOR AUTHORIZATION STATUS	Newly marketed or approved products that fall within a PDL drug class will be subject to non-preferred prior authorization criteria for the drug class and will be included as part of the next regularly scheduled P&T Committee and DUR Board reviews for that class. Newly marketed or approved products that fall within a drug category on appendix P (such as "Blood Products" or "Atypical Antipsychotic Injectables") will be subject to prior authorization criteria listed for medications in that drug category on Appendix P. For change in prior authorization status for a product that is not included in a PDL drug class or on Appendix P, notice will be given regarding DUR Board review of prior authorization criteria for the product as part of the posted DUR Board meeting agenda located at https://www.colorado.gov/pacific/hcpf/drug-utilization-review-board and posted at least 30 days prior to the DUR Board meeting during which the product is scheduled to be reviewed. Until such time that DUR Board review is conducted, products may receive prior authorization approval based on FDA-labeled indication, dose, age, and role in therapy as outlined in product package labeling. IV formulations or products where labeled use indicates that the medication should be administered by a healthcare professional will also be subject to meeting criteria for physician administered drugs (see "Physician Administered Drugs" section).	
NORTHERA (droxidopa)	**Northera** (droxidopa) will be approved if all the following is met:	3 months

	• Member has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) as defined by one of the following when an upright position is assumed or when using a head-up tilt table testing at an angle of at least 60 degrees. o At least a 20 mmHg fall is systolic pressure o At least a 10 mmHg fall in diastolic pressure AND • NOH caused by one of the following: o Primary autonomic failure (e.g, Parkinson's disease, multiple system atrophy, and pure autonomic failure o Dopamine beta-hydroxylase deficiency o Non-diabetic autonomic neuropathy AND • Member does not have orthostatic hypotension due to other causes (e.g, heart failure, fluid restriction, malignanacy) AND • Members has tried at least three of the following non-pharmacological interventions: o Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates, excluding SL symptom treatment formulations), alpha-adrenergic antagonists, and antidepressants] o Raising the head of the bed 10 to 20 degrees o Compression stockings o Increased salt and water intake, if appropriate o Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing) AND • Northera (droxidopa) is being prescribed by either a cardiologist, neurologist, or nephrologist AND • Member has failed a 30 day trail, has a contraindication, or intolerance to both Florinef (fludrocortisone) and ProAmatine (midodrine).	
NUCALA (mepolizumab)	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician's office must be billed as a medical expense. Because this medication has a FDA-labeled boxed warning requiring the administration under the supervision of a physician, a prior authorization will not be approved if administered in a member's home.	One year
NUEDEXTA (dextromethorphan /quinidine)	**Nuedexta** (dextromethorphan/quinidine) may be approved for members who meet the following criteria: • Nuedexta is being prescribed for diagnosis of pseudobulbar affect caused by an underlying neurologic condition (such as MS, ALS, or other underlying neurologic condition) AND • Member has a Center for Neurologic Study-Lability Scale (CNS-LS) score of 13 or higher AND • Member has frequent episodes of inappropriate laughing or crying per day before therapy AND • Member has a baseline electrocardiogram (ECG) with no significant abnormalities and no history of QT prolongation syndrome AND • Nuedexta is prescribed by a neurologist or in conjunction with a neurologist AND Member has trailed and failed one tricyclic antidepressant and one selective serotonin reuptake inhibitor within the past year (failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interactions)	Initial Approval: 3 months Continuation Approval: One year

	Initial approval will be given for 3 months and continued approval for one year may be given if member has 50% reduction in daily episodes at 3 months of therapy Nuedexta® Max Dose: 2 capsules (dextromethorphan 20mg/quinidine 10mg) per day given every 12 hours Renewal: members currently stabilized on this medication may continue to receive it with a documented diagnosis of pseudobulbar affect and evidence of efficacy (documentation of decrease in pseudobulbar episodes by 50% from baseline)	
OCREVUS (ocrelizumab)	**Ocrevus** (ocrelizumab) may be approved if the following criteria are met: • Ocrevus is being administered in a LTCF or in the member's home **AND** • <u>If prescribed for Relapsing Forms of Multiple Sclerosis (MS)</u> o Member is 18 years of age or older **AND** o Member has a relapsing form of multiple sclerosis **AND** o Member has experienced one relapse within the prior year or two relapses within the prior two years **AND** o Member has trial and failure of three of the following agents: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Tysabri (Natalizumab) or Lemtrada (alemtuzumab). Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following: o One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy o On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer **AND** • Ocrevus is prescribed by a neurologist or is prescribed in conjunction with a neurologist **AND** • <u>If prescribed for Primary Progressive Multiple Sclerosis</u> o Member is 18 years of age or older **AND** o Member is not concomitantly taking: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Tysabri (Natalizumab) or Lemtrada (alemtuzumab) **AND** • Member does not have active hepatitis B infection **AND** • Ocrevus is prescribed by a neurologist or is prescribed in conjunction with a neurologist Maximum maintenance dose: 600mg every 6 months	One year
OFEV (nintedanib)	**Ofev** (nintedanib) may be approved if all of the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis, chronic fibrosing interstitial lung disease with a progressive phenotype, or systemic sclerosis-associated interstitial lung disease (SSC-ILD) AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND	One year

	• Female members of reproductive potential must have been counseled regarding risk to the fetus and to avoid becoming pregnant while receiving treatment with Ofev and to use adequate contraception during treatment and at least 3 months after the last dose of Ofev AND • Member is not taking a P-gp or CYP3A4 inducer (e.g, rifampin, carbamazepine, phenytoin, St. John's Wort) Quantity Limits: 60 tablets/30 days	
ORILISSA (elagolix)	**Orilissa** (elagolix) may be approved for members meeting the following criteria: • Member is a premenopausal woman 18-49 years of age **AND** • Orilissa is not being prescribed for dyspareunia or any other sexual function related indication **AND** • Member has a definitive diagnosis of endometriosis as noted by surgical histology of lesions **AND** • Member has failed a 6-month trial of contraceptive agents (progestins, combined contraceptives, medroxyprogesterone acetate, levonorgestrel IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member has failed a 1 month trial of NSAIDs. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member has failed a 3 month trial with a GnRH agonist (such as leuprolide). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member is not pregnant, breast feeding, planning a pregnancy within the next 24 months, or less than 6 months post-partum, post-abortion, or post-pregnancy **AND** • Member has been instructed that only non-hormonal contraceptives should be used during therapy and for at least 1 week following discontinuation **AND** • Member does not have osteoporosis or severe hepatic impairment (Child-Pugh Class C) **AND** • Member is not concomitantly taking a OATP 1B1 inhibitor (such as gemfibrozil, cyclosporine, ritonavir, rifampin). Maximum Dose: 150mg tablet daily, or 200mg tablet twice daily Approval will be limited to a maximum treatment duration of 6 months for members with moderate hepatic impairment (Child-Pugh Class B).	One year 6 months for moderate hepatic impairment (Child Pugh Class B)
ORKAMBI (lumacaftor/ivacaftor)	**Orkambi** (lumacaftor/ivacaftor) may be approved for members if the following criteria has been met: • Member must have diagnosis of cystic fibrosis with genetic testing performed to confirm that member is homozygous for the F508del mutation in the CFTR gene AND • Member is 6 years of age or older AND • Member is being treated by a pulmonologist AND • Member has < 5 times upper limit of normal (ULN) AST/ALT or < 3 times ULN AST/ALT if concurrently has > 2 times ULN bilirubin at time of initiation AND • Member has serum transaminase and bilirubin measured before initiation and every 3 months during the first year of treatment	One year

ORIAHNN (elagolix, estradiol, norethindrone acetate)	**Oriahnn** (elagolix, estradiol, norethindrone acetate) prior authorization may be approved for members meeting the following criteria: • Member is a woman 18 years of age or older **AND** • Member has a confirmed diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** • Member has tried and failed treatment with an estrogen-progestin contraceptive (oral tablets, vaginal ring, transdermal patch) OR a progestin-releasing intrauterine device (IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • The medication is prescribed by or in consultation with an obstetrician/gynecologist **AND** • Member does not have a high risk of arterial, venous thrombotic, or thromboembolic disorder, including: o Women over 35 years of age who smoke **OR** o Women with a past or current history of the following: ▪ DVT, PE, or cerebrovascular disease (such as cerebrovascular disease, coronary artery disease, peripheral vascular disease) **OR** ▪ Thrombogenic valvular or thrombogenic rhythm diseases of the heart (such as subacute bacterial endocarditis with valvular disease, or atrial fibrillation) **OR** ▪ Inherited or acquired hypercoagulopathies **OR** ▪ Uncontrolled hypertension **OR** ▪ Headaches with focal neurological symptoms OR migraine headaches with aura if over age 35 **AND** • Member is not pregnant **AND** • Member does not have known osteoporosis **AND** • Member does not have current or history of breast cancer or other hormonally-sensitive malignancies **AND** • Member does not have known liver impairment or disease **AND** • Member is not concomitantly taking not an OATP 1B1 inhibitor (such as gemfibrozil, ritonavir, rifampin, cyclosporine) **AND** • Member has been counseled that that Oriahnn does not prevent pregnancy **AND** • Member has been instructed that only non-hormonal contraceptives should be used during Oriahnn therapy and for at least 1 week following discontinuation **AND** • Prescriber acknowledges that assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter, and discontinuation of Oriahnn should be considered if the risk associated with bone loss exceeds the potential benefit of treatment. Reauthorization: Members with current one-year prior authorization approval on file may receive additional one-year prior authorization approval to continue therapy. Total duration for prior authorization approvals is limited to 2 years (or two one-year approvals). Maximum dose: 2 capsules daily (AM and PM daily doses supplied in blister pack)	One year
OTC PRODUCTS*	The following OTC products do not require a prior authorization for coverage: o Aspirin	One year

	○ Oral emergency contraceptive products ○ Polyethylene glycol powder laxatives ○ Docusate (oral) *Effective 03/01/19* ○ Bisocodyl (oral and suppository) *Effective 03/01/19* ○ Children's liquid and chewable acetaminophen for ages 2-11 years ○ Children's liquid and chewable ibuprofen for ages 6 months – 11 years ○ Children's dextromethorphan suspension for ages 4-11 years ○ Nicotine replacement therapies (OTC patch, gum, and lozenge) The following OTC products may be covered with a prior authorization: • L-methylfolate may be approved for members with depression who are currently taking an antidepressant and are partial or non-responders • Nicomide may be approved for the treatment of acne • Cranberry tablets may be approved for urinary tract infections • Cough and Cold Products may be approved for members with a diagnosis of a chronic respiratory condition for which these medications may be prescribed or based on medical necessity supported by clinical practice recommendations • Guaifenesin 600mg LA may be approved for members having an abnormal amount of sputum • Bisacodyl enema may be approved following adequate trial and/or failure with a bisocodyl oral formulation and bisocodyl suppository (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects, or significant drug-drug interactions). *Effective 03/01/19* • Docusate enema may be approved following adequate trial and with a docusate oral formulation (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects, or significant drug-drug interactions). *Effective 03/01/19* • Ferrous sulfate and ferrous gluconate may be approved with diagnosis iron deficient anemia OR iron deficiency verified by low serum ferritin. *Effective 03/01/19* • Members with erythema bullosum (EB) may be approved to receive OTC medications (any Medicaid rebate-eligible OTC medications) Other OTC product coverage information: • Diabetic needles and supplies are covered under the DME benefit • Broncho saline: *See Sodium Chloride section* • Fluoride supplements: *See Fluoride Products section* • OTC Proton Pump Inhibitors: *See PDL* • OTC Combination Antihistamine/Decongestant Products: *See PDL* • Long Term Care Facilities (LTCFs): Various OTC drugs and supplies for LTCF residents shall be furnished by the facility, within the per diem rate, at no charge to the resident pursuant to 10 CCR 2505-10 Skilled Nursing Facility: 8.440 NURSING FACILITY BENEFITS. These OTC drugs and supplies, known as products on a "floor stock list", are not covered or eligible for prior authorization under the pharmacy benefit for LTCF members. ** Coverage criteria outlined in this section apply to prescriptions written by non-pharmacist prescribers. For coverage relating to pharmacist prescribers please see "Pharmacist Prescriptions" section.*	
OXANDRIN (oxandrolone)	**Oxandrin** (oxandrolone) may be approved if meeting all of the following criteria: • Medication is being prescribed for one of the following indications: ○ As adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, severe trauma, and	One Year

	without definite pathophysiologic reasons to fail to gain or maintain normal weight o To offset the protein catabolism associated with prolonged administration of corticosteroids o For the relief of bone pain frequently accompanying osteoporosis AND • Member does not have any of the following medical conditions: o Hypercalcemia o Known or suspected carcinoma of the prostate or the male breast o Carcinoma of the breast in females with hypercalcemia o Nephrosis, the nephrotic phase of nephritis AND • If member is female, has had a negative pregnancy test within the past month AND • Medication is being prescribed by or in consultation with an endocrinologist. Maximum Dose: Adults: 20mg daily for 4 weeks Children: ≤ 0.1 mg/kg per day for 4 weeks Adults ≥ 65 years old: 10mg daily for 4 weeks	
OXBRYTA (voxelotor)	**Oxbryta** (voxelotor) prior authorization may be approved for members meeting the following criteria: • Member is ≥ 12 years of age **AND** • Member has a confirmed diagnosis of sickle cell disease **AND** • Member has a hemoglobin ≥ 5.5 g/dL **AND** • OXBRYTA is prescribed by or in consultation with hematologist/oncologist or sickle cell disease specialist **AND** • Prior to initiation of therapy, member had at least two episodes of sickle cell related pain crises in the past 12 months **AND** • Member has trialed and failed a six-month trial of hydroxyurea (intolerance or contraindication) or is continuing concomitant hydroxyurea therapy following a six-month trial. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member is not receiving chronic transfusion therapy **OR** • Member has severe renal disease (GFR <30 mL/min) Initial approval: 6 months Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Member has a reduction in vasoocclusive events and/or increased hemoglobin response rate defined as a hemoglobin increase of more than 1 g/dL. Maximum dose: 1,500 mg per day (2,500 mg per day may be approved for members taking concomitant strong or moderate CYP3A4 inducers (such as carbamazepine, oxcarbazepine, phenytoin, phenobarbital, rifaximin, rifampin or dexamethasone-containing products).	Initial: 6 months Continued: One year
OXERVATE (cenegermin-bkbj)	**Oxervate** (cenegermin-bkbi) prior authorization may be approved for members meeting the following criteria: • Member is 2 years of age or older **AND**	8 weeks

	• Member has a confirmed diagnosis of stage 2 neurotrophic keratitis (NK), persistent epithelial defect [PED], or stage 3 neurotrophic keratitis (corneal ulcers) **AND** • Oxervate is being prescribed in consultation with an ophthalmologist or optometrist **AND** • Member's PED and/or corneal ulcer have been present for at least two weeks **AND** • Member has trialed and failed one of the following conventional non-surgical treatments: preservative-free lubricant eye drops or ointment, therapeutic soft contact lenses, or topical autologous serum application. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Member has decreased corneal sensitivity (≤4 cm using the Cochet-Bonnet esthesiometer) within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant **AND** • Prescriber attests to member's discontinued use of preserved topical agents that can decrease corneal sensitivity **AND** • Member <u>does not</u> have any of the following: o Active ocular infection or active inflammation not related to NK in the affected eye o Schirmer test without anesthesia ≤3 mm/5 min in the affected eye o Any ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK o Corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting Maximum dose: 12 drops daily	
OXSORALEN (methoxsalen)	**Oxsoralen** (methoxsalen) prior authorization may be approved for the following diagnoses: Myosis; Fungoides; Psoriasis or Vitiligo	One year
PALFORZIA (arachis hypogaea allergen powder-dnfp)	**Palforzia (**arachis hypogaea allergen powder-dnfp**)** prior authorization may be approved for members meeting the following criteria: • Member is 4 -17 years of age at initiation of therapy **AND** • Member has a documented diagnosis of peanut allergy within the past 2 years (ICD-10 Z91.010) **AND** • Diagnosis of peanut allergy is made by or in consultation with an allergist or immunologist **AND** • Palforzia will be used in conjunction with a peanut-avoidant diet **AND** • Member <u>does not</u> have a past or current history of any of the following: o Severe, unstable or uncontrolled asthma o Eosinophilic esophagitis or other eosinophilic gastrointestinal disease o Mast cell disorder including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema o Severe or life-threatening anaphylaxis within the previous 60 days **AND** • Member has injectable epinephrine available for immediate use at all times and counseling regarding proper use has been provided **AND** • Prescriber acknowledges member preparedness to adhere to complex up-dosing schedule and frequent visits to the administering healthcare facility **AND** • Prescriber acknowledges that Palforzia doses administered by a healthcare provider in the doctor's office or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process.	One year

	Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Palforzia continues to be used in conjunction with a peanut-avoidant diet **AND** • Member continues to tolerate the prescribed daily doses of Palforzia **AND** • Member continues to have injectable epinephrine available for immediate use at all times **AND** • Member has not experienced recurrent asthma exacerbations **AND** • Member does not have eosinophilic esophagitis or other eosinophilic gastrointestinal disease **AND** • Member does not have a mast cell disorder including mastocytosis, urticarial pigmentosa, and/or hereditary/idiopathic angioedema **AND** • Member has not experienced any treatment-restricting adverse effects (such as repeated systemic allergic reaction and/or severe anaphylaxis) Maximum dose (maintenance): 300 mg daily	
PALYNZIQ (pegvaliase-pqpz)	**Palynziq** (pegvaliase-pgpz) prior authorization may be approved for members meeting the following criteria: • Member is at 18 years of age or older **AND** • Member has a diagnosis of phenylketonuria (PKU) **AND** • Member has a blood phenylalanine concentration > 600 mcmol/L **AND** • Member is not receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride) **AND** • Member is actively on a phenylalanine-restricted diet **AND** • Member will have a phenylalanine blood level measured at baseline prior to initiation and every four weeks until a maintenance dose is established **AND** • Prescriber acknowledges that first dose is being administered under the supervision of a healthcare provider equipped to manage anaphylaxis **AND** • Prescriber acknowledges that any doses administered in the doctor's office or clinic are to be billed to the Health First Colorado medical benefit through the standard buy-and-bill process. Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Member is showing signs of continuing improvement, as evidenced by one of the following: o Blood phenylalanine level decrease of at least 20% from pre-treatment baseline **OR** o Reduction of blood phenylalanine below 600 mcmol/L at current dose or maximum dose after 16 weeks of treatment. Maximum dose: 40 mg per day	One year
PCSK9 INHIBITORS Praluent, Repatha	PCSK9 inhibitors may be approved for members that meet the following criteria: • Medication is prescribed for one of the following diagnoses: o **Praluent** (alirocumab): heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease o **Repatha** (evolocumab): heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (defined below) Conditions Which Define Clinical Atherosclerotic Cardiovascular Disease	Initial Approval: 3 months Continuation Approval: One year

	• Acute Coronary Syndrome
	• History of Myocardial Infarction
	• Stable or Unstable Angina
	• Coronary or other Arterial Revascularization
	• Stroke
	• Transient Ischemic Attach
	• Peripheral Arterial Disease of Atherosclerotic Origin
	
	• PCSK9 inhibitor therapy is prescribed by, or in consultation with, one of the following providers:
	  o Cardiologist
	  o Certified Lipid Specialist
	  o Endocrinologist AND
	• Member is concurrently adherent (>80% of the past 180 days) on maximally tolerated dose (see table below) of statin therapy (must include atorvastatin and rosuvastatin). If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other statins. For members with a past or current incidence of rhabdomyolysis, one month failure is not required AND
	• Member must be concurrently treated (in addition to maximally tolerated statin) with ezetimibe AND have a treated LDL $\geq$ 70 mg/dl for a clinical history of ASCVD or LDL $\geq$ 100 mg/dl if familial hypercholesterolemia AND
	• PA will be granted for 3 months initially. Additional one year approval for continuation will be granted with provider attestation of safety and efficacy with initial medication therapy
	
	Atorvastatin 80mg
	Fluvastatin 80 mg
	Lovastatin 80 mg
	Pravastatin 80 mg
	Rosuvastatin 40 mg
	Simvastatin 40 mg (80 mg not used in practice)	

PHARMACIST PRESCRIPTIONS	The following OTC products will be covered with a written prescription by a pharmacist:
	• Oral emergency contraceptive products
	• Nicotine replacement therapy products including:
	  o Nicotine gum (up to 200 units/fill)
	  o Nicotine patch (up to 30 patches/30days)
	  o Nicotine lozenge (up to 288 units/fill)
	• Children's dextromethorphan suspension for members age 4-11 years (up to 150 ml per 30 days)
	• Children's liquid and chewable acetaminophen for members age 2-11 years (up to 240 ml per 30 days)
	• Children's liquid and chewable ibuprofen for members age 6 months – 11 years (up to 240 mL per 30 days)	

PHYSICIAN ADMINISTERED DRUGS	Medications administered in a doctor's office, clinic, outpatient hospital, or dialysis unit are only to be billed by those facilities through the Health First Colorado medical benefit using the standard buy-and-bill process and following procedures outlined in the PAD Billing Manual (located at https://www.colorado.gov/hcpf/physician-administered-drugs). Physician administered drugs include any medication or medication formulation that is administered intravenously or requires administration by a healthcare professional (including cases where FDA package labeling for a medication specifies that	

	administration should be performed by or under the direct supervision of a healthcare professional) and may only be billed through the pharmacy benefit when given in a long-term care facility or when administered in the member's home by a healthcare professional or home health service. Prior authorization for physician administered drugs requires documentation of the following (in addition to meeting any other prior authorization criteria if listed): • For drugs administered in the member's home by a home health agency or healthcare professional (home health administered): 1. Name of home health agency or healthcare professional 2. Phone number 3. Date and authorization number for home health authorization on file (when applicable for home health agencies) • For drugs administered in a long-term care facility: 1. Name of long-term care facility 2. Phone number of long-term care facility	
PRETOMANID	**Pretomanid** prior authorization may be approved for members meeting the following criteria: • Member is an adult (≥ 18 years of age) **AND** • Member has a confirmed diagnosis of multidrug resistant tuberculosis **AND** • Pretomanid is prescribed by or in conjunction with an infectious disease specialist **AND** • Pretomanid is prescribed in combination with bedaquiline and linezolid by directly observed therapy (DOT) **AND** • Prescriber acknowledges member readiness and anticipated compliance with undergoing directly observed therapy (DOT) **AND** • Prescriber acknowledges that Pretomanid doses administered by a healthcare provider in a hospital, doctor's office, or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process. Maximum dose: 200 mg orally once daily	One year
PREVYMIS (letermovir)	**Prevymis** (letermovir) may be approved for members that meet the following criteria: • Member is a CMV-seropositive transplant recipient and meets ALL of the following: AND o Member is 18 years or older. o Member has received an allogeneic hematopoietic stem cell transplant. o Member does not have severe hepatic impairment (Child-Pugh Class C). o Member is not receiving pitavastatin or simvastatin co-administered with cyclosporine. o Member is not receiving pimozide or ergot alkaloids. • Prevymis® is being prescribed by or in consultation with an oncologist, hematologist, infectious disease specialist, or transplant specialist. AND • Provider agrees to monitor for CMV reactivation. AND • Prevymis® dose does not exceed 480 mg orally or dose does not exceed 240mg if co-administered with cyclosporine. AND • If request is for IV injectable Prevymis®, must provide medical justification why the patient cannot use oral therapy. AND • If request is for IV injectable Prevymis®, must be administered in a long-term care facility or in a member's home by a home healthcare provider Length of Approval: Prevymis® will only be approved for 100 days	100 days

	Renewal: Authorization may be reviewed every 100 days to confirm that current medical necessity criteria are met and that the medication is effective (e.g. no evidence of CMV viremia).	
PROCYSBI (cysteamine)	Approval will be granted if the member is 2 years of age or older **AND** Has a diagnosis of nephropathic cystinosis **AND** documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.	One year

PROMACTA (eltrombopag)	**Promacta** (eltrombopag) prior authorization may be approved for members meeting criteria for the following diagnoses:
	
	<u>Chronic immune idiopathic thrombocytopenia purpura:</u>
	• Confirmed diagnosis of chronic (> 3 months) immune idiopathic thrombocytopenia purpura AND
	• Must be prescribed by a hematologist AND
	• Member is at risk (documented) of spontaneous bleed as demonstrated by the following labs: AND
	  o Platelet count less than 20,000/mm3 or
	  o Platelet count less than 30,000/mm3 accompanied by signs and symptoms of bleeding
	• In the past 6 months, member has tried and failed (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) systemic corticosteroids (e.g. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days), immunoglobulin replacement, or splenectomy.
	
	<u>Thrombocytopenia associated with hepatitis C:</u>
	• Member must have confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND
	• Must be prescribed by a gastroenterologist, infectious disease specialist, transplant specialist or hematologist AND
	• Member has clinically documented thrombocytopenia defined as platelets < 60,000 microL AND
	• Patients' degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy
	
	<u>Severe aplastic anemia:</u>
	• Member must have confirmed diagnosis of severe aplastic anemia AND
	• Must be prescribed by a hematologist AND
	• Member must have had a documented insufficient response to immunosuppressive therapy [antithymocyte globulin (ATG)] alone or in combination with cyclosporine and/or a corticosteroid
	
	*All initial prior authorization approvals will be granted for 12 months. Further approvals for a maximum of 6 months require lab results and documentation for efficacy.
		One year*

PROMETHAZINE	A Prior authorization is required for all routes of administration for members under the age of two. Children under the age of two should not use Promethazine. Promethazine is contraindicated in such patients because of the potential for fatal respiratory depression. Not qualified for emergency 3 day supply PA	One year
PROPECIA (finasteride)	***Not covered for hair loss*** *Not qualified for emergency 3 day supply PA*	One year
PULMOZYME (dornase alfa)	**Pulmozyme** (dornase alfa) may be approved for members that meet the following criteria: • Member has a diagnosis of cystic fibrosis AND • Member is five years of age or older o For children < 5 years of age, Pulmozyme will be approved if the member has severe lung disease as documented by bronchoscopy or CT scan Pulmozyme twice daily will only be approved if patient has tried and failed an adequate trial of once daily dosing for one month All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon documentation from the prescriber that the member continues to benefit from Pulmozyme therapy. Quantity Limits: 30 ampules (2.5 mg/2.5 ml) per month	

QBREXZA (glycopyrronium)	**Qbrexza** (glycopyrronium) prior authorization may be approved for members meeting the following criteria:
	• Member is 9 years of age or older **AND**
	• Member has a diagnosis of primary hyperhidrosis occurring more than once weekly and symptoms cease at night **AND**
	• Member has a documented Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 **AND**
	• There is documentation that the axillary hyperhidrosis is severe, intractable and disabling in nature as documented by at least one of the following:
	  o Significant disruption of professional and/or social life as a result of excessive sweating **OR**
	  o The condition is causing persistent or chronic cutaneous conditions (such as skin maceration, dermatitis, fungal infections, secondary microbial infections)
	AND
	• Prescriber has considered a trial of OTC topical antiperspirants (such as 20% aluminum chloride hexahydrate,15% aluminum chloride hexahydrate, or 6.25% aluminum chloride hexahydrate)
	
	Initial approval: 3 months
	
	Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following:
	• Member has documented improvement of at least two points in Hyperhidrosis Disease Severity Scale (HDSS) score following initiation (or ongoing use) of Qbrexza regimen.
	
	Maximum dose: 1 cloth per day
		Initial:
		3 months
		
		Continued:
		One year

RADICAVA (edaravone)	**Radicava** (edaravone) may be approved for members that meet the following criteria: • RADICAVA is being administered in a long-term care facility or in a member's home by a home healthcare provider AND • Member has a "definite" or "probable" diagnosis of amyotrophic lateral sclerosis (ALS) based on medical history and diagnostic testing which may include imaging and nerve conduction conditions studies AND • Member meets ALL of the following: o Member has a diagnosis of ALS for 2 or less years (for new starts only). o Diagnosis has been established by or with the assistance of a neurologist with expertise in ALS using El Escorial or Airlie House diagnostic criteria (ALSFRS-R). o Member has normal respiratory function as defined as having a percent-predicated forced vital capacity of greater than or equal to 80%. o The ALSFRS-R score is greater than or equal to 2 for all items in the criteria. o Member does not have severe renal impairment (CrCl< 30 ml/min) or end stage renal disease o Member does not have moderate or severe hepatic impairment (Child-Pugh Class C) AND • RADICAVA is prescribed by or in consultation with a neurologist. Length of Approval: 6 months. Quantity Limits: For patients initiating therapy, approval will include 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months. Renewal: Authorization may be reviewed every six months to confirm that current medical necessity criteria are met and that the medication is effective per improvement in ALSFRS-R score.	6 months
RANITIDINE Capsule/Solution	Prescription ranitidine capsule and liquid formulations require prior authorization. <u>Ranitidine capsule</u>: Require the prescribing provider to certify that capsules are medically necessary and that the member cannot use the tablets. <u>Ranitidine liquid</u>: A prior authorization will be approved for members with a feeding tube or who have difficulty swallowing. A prior authorization is not required for children under 12 years of age.	One year
RAVICTI (glycerol phenylbutyrate)	**Ravicti** (glycerol phenylbutyrate) will only be approved for members meeting the following criteria: • Member must have a documented diagnosis of urea cycle disorder (UCD) • Member must be on a dietary protein restriction (verified by supporting documentation) • Member must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days • Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist)	One year
REBATE DISPUTE DRUGS	Medical necessity. Not qualified for emergency 3 day supply PA	One year

REVCOVI (elapegademase-lvlr)	**Revcovi** (elepegademase-lvlr) may be approved for members meeting the following criteria: of adenosine deaminase severe combined immune deficiency (ADA-SCID). Maximum dose: Revcovi 0.4mg/kg per week (based on ideal body weight, IM administration)	One year
RUZURGI (amifampridine)	**Ruzurgi** (amifampridine) may be approved for members meeting the following criteria: • Member is 6 to less than 17 years of age AND • Member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) Maximum dose: 100mg daily	One year
SANDOSTATIN (octreotide)	Approved for acromegaly; carcinoid tumors; and vasoactive intestinal peptide tumors.	Lifetime
SILENOR (doxepin tablet)	**Silenor** (doxepin) tablets may be approved if a member meets ONE of the following criteria: • Contraindication to preferred oral sedative hypnotics (see preferred drug list "Sedative Hypnotic" class for list of preferred products) OR • Prescriber attests to the medical necessity for use of doxepin dose < 10 mg OR • Member age is greater than 65 years	One year
SIVEXTRO (tedizolid)	**Sivextro** may be approved for members ≥ 12 years of age if all of the following criteria are met: • Member has diagnosis of acute bacterial skin and skin structure infection (ABSSSI) caused by one of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus* Group (including *Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), and *Enterococcus faecalis.* AND • Member has adequate trial and/or failure of linezolid 600mg twice daily for 10 days. Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions Maximum dosing: 200mg daily for 6 days total duration	Six months
SODIUM CHLORIDE (Inhalation)	Broncho Saline is not covered under the pharmacy benefit. Sodium chloride (inhalation use) must be billed through medical.	N/A
SOLIRIS (eculizumab)	**Soliris** (ecluizumab) may be approved for members meeting all of the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Mysthenia Gravis (gMG), or Neuromyleitis Optica Spectrum Disorder (NMOSD) AND • Member does not have a systemic infection AND • Member must be administered a meningococcal vaccine at least two weeks prior to initiation of Soliris therapy and revaccinated according to current medical guidelines for vaccine use AND • Prescriber is enrolled in the Soliris (eculizumab) Risk Evaluation and Mitigation Strategy (REMS) program AND	One year

- Medication is prescribed by or in conjunction with a hematologist for PNH and by or in conjunction with a hematologist or nephrologist for aHUS and by or in conjunction with a neurologist for gMG or NMOSD AND
- Member meets criteria listed below based on specific diagnosis:

Paroxysmal Nocturnal Hemoglobinuria

- Member is 18 years of age or older AND
- Diagnosis of PHN must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND
- Member demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes) AND
- Member has one of the following indications for therapy:
  - Presence of a thrombotic event
  - Presence of organ damage secondary to chronic hemolysis
  - Patient is pregnant and potential benefit outweighs potential fetal risk
  - Patient is transfusion dependent
  - Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms

AND

- Member has documented baseline values for one or more of the following:
  - Serum lactate dehydrogenase (LDH)
  - Hemoglobin level
  - Packed RBC transfusion requirement

Atypical Hemolytic Uremic Syndrome

- Member is 2 months or older AND
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level (ADAMTS-13 activity level > 10%); AND
- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out; AND
- Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency AND
- Documented baseline values for one or more of the following:
  - Serum lactate dehydrogenase (LDH)
  - Serum creatinine/eGFR
  - Platelet count
  - Plasma exchange/infusion requirement

Generalized Myasthenia Gravis

- Member is 18 years or older AND
- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND

	• Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; AND • Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; AND • Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND • Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) <u>Neuromyelitis Optica Spectrum Disorder</u> • Member is 18 years or older AND • Member has a past medical history of one of the following: o Optic neuritis o Acute myelitis o Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting o Acute brainstem syndrome o Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions o Symptomatic cerebral syndrome with NMOSD-typical brain lesions AND • Member has a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies; AND • Diagnosis of multiple sclerosis or other diagnoses have been ruled out AND • Member has not failed a previous course of Soliris (eculizumab) therapy AND • Member has a history of failure, contraindication, or intolerance to rituximab therapy AND • Member has at least one of the following: o History of at least two relapses during the previous 12 months prior to initiating Soliris (eculizumab) o History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris (eculizumab) AND • Member is not receiving Soliris in combination with any of the following: o Disease modifying therapies for the treatment of multiple sclerosis (such as Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.) OR o Anti-IL6 therapy Maximum dose: 900mg weekly for 4 weeks induction followed by 1200mg every 2 weeks maintenance dose	
SOLOSEC (secnidazole)	**Solosec** (secnidazole) may be approved for members meeting the following criteria:	One year

	• Solosec® is being prescribed for bacterial vaginosis in an adult female member **AND** • Member has adequately trialed and failed an oral OR topical formulation of metronidazole (Failure is defined as lack of efficacy of a 7 day trial, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy) **AND** • Member has adequately trialed and failed an oral OR topical formulation of clindamycin (Failure is defined as lack of efficacy of a 7 day trial, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy) Solosec® Maximum Quantity: 1 packet of 2 grams per 30 days	
STRENSIQ (asfotase alfa)	**Strensiq** (asfotase alfa) may be approved if all of the following criteria are met: Member has a diagnosis of either perinatal/infantile- OR juvenile-onset hypophosphatasia (HPP) based on all of the following a. Member was ≤ 18 years of age at onset b. Member has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g. vitamin B6-dependent seizures, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, "failure to thrive"). c. Member has/had radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis) d. Member has one of the following: elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test, or elevated urinary inorganic pyrophosphate (PPi) AND e. Molecular genetic test has been completed confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) within 30 days of initiation. If genetic test is negative, approval will not be granted past 30 days. f. Prescriber is a specialist in the area of the members disease (such as an endocrinologist)	Six months
SYMDEKO (tezacaftor/ivacaftor and ivacaftor)	**Symdeko** (tezacaftor/ivacaftor and ivacaftor) may be approved for members that meet the following criteria: • The member has a diagnosis of cystic fibrosis AND • The member is 6 years of age or older AND • The member has one of the following mutations: o Homozygous for the F508del mutation in the CFTR gene 2 OR o Heterozygous for the F508del mutation in the CFTR gene and one of the following mutations: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D1270N, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, 3272-26A-G, 2789+5G-A, 3849-10kbC-T, or another FDA approved gene mutation AND • Member has ALT, AST, and bilirubin at baseline and tested every 3 months for the first year AND • Member has a baseline ophthalmological examination and periodic follow-up exams for cataracts AND	One year

	• Must be prescribed by or in consultation with a pulmonologist or gastroenterologist AND • Member is not receiving dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator AND • Member has had 2 negative respiratory cultures for any of the following organisms: *Burkholeria cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus* in the past 12 months.	
SYNAGIS (palivizumab)	**Pharmacy prior authorization requests for Synagis must be submitted by fax using the Synagis prior authorization form found at https://www.colorado.gov/hcpf/provider-forms and is for home or long-term care facility administration only. The 2021-2022 Synagis season will begin August 17, 2021. A maximum of five (5) doses will be approved. The Department will continue to monitor RSV reporting and reassess Health First Colorado member needs and season end date based on CDC virology reporting and AAP guidance.** **Synagis given in a doctor's office, hospital or dialysis unit is to be billed directly by those facilities as a medical benefit. Medical prior authorization requests must be submitted at https://hcpf.colorado.gov/par. Synagis may only be a pharmacy benefit if the medication is administered in the member's home or long-term care facility.** **Key Points** 1. No more than 5 doses per season. 5 doses provide more than 6 months of protective serum concentration. 2. Synagis is not recommended for controlling outbreaks of health care-associated disease. 3. Synagis is not recommend for prevention of health care-associated RSV disease. 4. Infants born later in the season may require less than 5 doses to complete therapy to the end of the season. 5. Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization. 6. Synagis is not recommended to prevent wheezing, nosocomial disease, or treatment of RSV 7. Synagis is not routinely recommended for patients with a diagnosis of Down syndrome unless they also have a qualifying indication listed below. 8. In the **first year of life** Synagis is recommended: a. For infants born before 29w 0d gestation. b. For infants born before 32w 0d **AND** with chronic lung disease (CLD) of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth. c. For infants with hemodynamically significant heart disease (acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures or infants with moderate to severe pulmonary hypertension**) AND** born within 12 months of onset of the RSV season. d. Infants who undergo cardiac transplantation during the RSV season. e. For infants with cyanotic heart defects **AND** in consultation with a pediatric cardiologist **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) f. If an infant has neuromuscular disease or pulmonary abnormality **AND** is unable to clear secretions from the upper airways	Maximum of 5 doses per season

	g. An infant who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) h. An infant with cystic fibrosis with clinical evidence of CLD **AND/OR** nutritional compromise 9. In the **second year of life** Synagis is recommended for: a. Children born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) b. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) c. Children with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) **OR** weight for length less than the 10th percentile. d. Children who undergo cardiac transplantation during the RSV season.	
SYPRINE (trientine)	**Syprine** (trientine) may be approved if all of the following criteria are met: • Must be prescribed in conjunction with a gastroenterologist, hepatologist, or liver transplant specialist. **AND** • Member has a diagnosis of Wilson's Disease meeting at least one of the following criteria: o Hepatic parenchymal copper content of ≥250µg/g dry weight o Presence of Kayser-Fleischer Ring in cornea o Serum ceruloplasmin level <50mg/L o Basal 24-hour urinary excretion of copper >100µg (1.6 µmoles) o Genetic testing results indicating mutation in ATP7B gene **AND** • Member has failed a three-month trial or is intolerant to penicillamine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND** • Member has failed a three-month trial or is intolerant to generic trientine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.	One year
TAMIFLU (oseltamivir) capsules	Effective 10/15/2019: Claims for brand Tamiflu® capsules require prior authorization approval (see section "Brand Name Medications and Generic Mandate" for brand product coverage details). Generic equivalent oseltamivir formulations do not require prior authorization.	
TAVALISSE (fostamatinib)	**Tavalisse** (fostamatinib) prior authorization may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a documented diagnosis of chronic immune thrombocytopenia AND • Member has trialed and failed at least ONE of the following therapies (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions): o Promacta (eltrombopag) or other thrombopoietin receptor agonist o Corticosteroids o Immunoglobulin o Splenectomy AND	Initial Approval: 3 months Continuation Approval: One year

	• Baseline platelet count prior to initiation is less than $30x10^9$/L or $30x10^9$/L to $50x10^9$/L with symptomatic bleeding AND • Prescriber attests to monitoring liver function tests and CBC monthly until a stable dose is achieved AND • Tavalisse (fostamatinib) is not being used as dual therapy with a thrombopoietin receptor agonist AND • Tavalisse (fostamatinib) is being prescribed by or in consultation with a hematologist AND • Initial prior authorization approval will be for 3 months. Continuation may be approved with verification of documented platelet response (platelet count ≥50x109/L) Quantity Limit: 60 tablets per 30 days	
TARGETED IMMUNE MODULATORS (IV and physician-administered products)	**Actemra** (tocilizumab) **IV injection** may be approved if meeting the following criteria: • Actemra is being prescribed for an FDA-labeled indication (per product package labeling) AND • Member has trialed and failed ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication (failure is defined as lack of efficacy of a three-month trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interaction) AND • Actemra IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility **Entyvio** (vedolizumab) may be approved for members who are receiving infusion in their home or in a long-term care facility and who meet the following criteria: • Medication is being used in an adult member with ulcerative colitis or Crohn's disease AND • For diagnosis of **Crohn's disease**, have trialed and failed‡ Humira and Cimzia OR for a diagnosis of **ulcerative colitis**, have trialed and failed‡ Humira and Simponi AND • Member has had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids AND • Member is not receiving Entyvio in combination with Humira, Simponi, or Tysabri AND • Medication is initiated and titrated per FDA-labeled dosing for Crohn's Disease and Ulcerative Colitis up to a maximum of 300mg IV infusion every 8 weeks **Inflectra** (infliximab dyyb) may be approved with trial & failure‡ of Renflexis (infliximab abda) AND if meeting all of the following criteria: • Medication is being administered in the member's home or in a long-term care facility AND • Member has one of the following diagnoses: o Crohn's disease and is 6 years or older o Ulcerative colitis and is 6 years or older o Rheumatoid arthritis and is 4 years or older o Psoriatic arthritis in adults o Ankylosing spondylitis in adults o Juvenile idiopathic arthritis o Plaque psoriasis in adults AND	One year (for Stelara, see criteria)

- Member has tried and failed‡ ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication

Orencia (abatacept) – may be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following:

- Member has a diagnosis of moderate to severe rheumatoid arthritis or polyarticular juvenile idiopathic arthritis AND has trialed and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR
- Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira or Enbrel AND Xeljanz IR AND Taltz or Otezla.

Remicade (infliximab) may be approved with trial & failure‡ of Renflexis (infliximab abda) AND if meeting all of the following criteria:

- Medication is being administered in the member's home or in a long-term care facility AND
- Member has one of the following diagnoses:
  - Crohn's disease and is 6 years or older
  - Ulcerative colitis and is 6 years or older
  - Rheumatoid arthritis and is 4 years or older
  - Psoriatic arthritis in adults
  - Ankylosing spondylitis in adults
  - Juvenile idiopathic arthritis
  - Plaque psoriasis in adults

  AND
- Member has tried and failed‡ ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication.

Renflexis (infliximab abda) may be approved if meeting all of the following criteria:

- Medication is being administered in the member's home or long-term care facility AND
- Member has one of the following diagnoses:
  - Crohn's disease and is 6 years or older
  - Ulcerative colitis and is 6 years or older
  - Rheumatoid arthritis and is 4 years or older
  - Psoriatic arthritis in adults
  - Ankylosing spondylitis in adults
  - Juvenile idiopathic arthritis
  - Plaque psoriasis in adults

  AND
- Member has tried and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication.

Rituxan (rituximab) IV and subcutaneous - will be approved for administration in a long-term care facility or in a member's home by a home healthcare provider AND for members who meet one of the following:

- Have diagnosis of moderate to severe rheumatoid arthritis AND have tried and failed both Enbrel and Humira OR
- Have diagnosis of chronic lymphocytic leukemia OR
- Have a diagnosis of Non-Hodgkins Lymphoma

	Stelara (ustekinumab) **IV injection** may be approved if meeting the following criteria: • Stelara is being prescribed for an FDA-labeled indication (per product package labeling) AND • Member has trialed and failed‡ ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication AND • Stelara IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Initial prior authorization approval may be given for 16 weeks. Prior authorization for one year may be approved for continuation of therapy based on clinical response. **Simponi** (golimumab) **IV injection** may be approved if meeting the following criteria: • Simponi IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member has tried and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication. ‡Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor.	
THIOLA EC (tiopronin DR)	**Thiola EC** (tiopronin DR) may be approved for members meeting the following criteria: Member is an adult or pediatric weighing 20kg or more AND Member has severe homozygous cystinuria AND Member has increased fluid intake and diet modifications have been implemented for the prevention of cysteine stone formation AND Member has trial and failure of urinary alkalization agent (such as potassium citrate or potassium bicarbonate) AND • Member has trial and failure of Thiola IR (tiopronin). Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects or significant drug-drug interactions. Maximum dose: Thiola EC 1500mg per day	One year
THROMBOLYTIC ENZYMES	Approved for **IV Catheter Clearance or Occluded AV Cannula** if given in member's home or long term care facility.	One year
TOBACCO CESSATION	Effective 11/01/18 prior authorization will not be required for tobacco cessation medications including nicotine gum, nicotine patch, nicotine lozenge, nicotine inhaler (Nicotrol®), varenicline (Chantix®), and bupropion SR (Zyban®). Smoking and tobacco cessation resources are available at no charge to members or providers through the Colorado QuitLine found at coquitline.org or by calling 1-800-QUIT-NOW.	
TRIKAFTA	**Trikafta** may be approved for members meeting the following criteria: • Member is 12 years of age or older AND	One year

(elexacaftor, tezacaftor, ivacaftor)	• Member has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CTFR) gene or a mutation in the CFTR gene that is responsive based on in vitro data AND • Member continues to receive standard of care CF therapies (such as bronchodilators, inhaled antibiotics, dornase alfa, and hypertonic saline) AND • Member must have liver function tests checked within 3 months without abnormal results (ALT, AST, ALP, or GGT ≥ 3 × ULN, or total bilirubin ≥2 × ULN) AND • Baseline Forced Expiratory Volume (FEV1) must be collected Maximum Dose: 84 tablets per 28 days	
TPN PRODUCTS	Approval will be given if included as part of TPN therapy administered in the member's home or in a long-term care facility by a home healthcare provider. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
TYBOST (cobicistat)	**Tybost** may be approved for members meeting the following criteria: • Member has a diagnosis of HIV-1 AND • Member is currently being treated with atazanavir or darunavir only AND • Member is not taking cobicistat-containing drugs, or ritonavir-containing drugs AND • Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or lack of efficacy).	One year
TYSABRI (natalizumab)	**Tysabri** (natalizumab) will be approved for initial therapy if the following criteria are met: • Tysabri is being administered in a long-term care facility or in home-health setting **AND** • Medication is not currently being used in combination with immunosuppresants (azathioprine, 6-mercaptopurine, methotrexate) or TNF-alpha inhibitors (adalimumab, certolizumab pegol, infliximab) **AND** <u>If prescribed for induction of remission of moderate to severe Crohn's disease</u> • The patient is ≥ 18 years of age **AND** • Member has tried and failed Aminosalicylates **AND** • Member has tried and failed Corticosteroids **AND** • Member has tried and failed immunomodulators **AND** • Member has tried and failed two TNF-alpha inhibitors (e.g. adalimumab, • certolizumab pegol, infliximab) **AND** • Tysabri is prescribed by or in consultation with a gastroenterologist. <u>If prescribed for relapsing remitting multiple sclerosis (RRMS)</u> • The patient is ≥ 18 years of age; **AND** • Member has trial and failure of three of the following agents: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Ocrevus (ocrelizumab) or Lemtrada (alemtuzumab). Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy indicated by one of the following: o One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy o On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer **AND**	One year

	• Tysabri is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis	
ULTOMIRIS (ravulizumab)	**Ultomiris** (ravulizumab) may be approved for members meeting the following criteria: Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member has a diagnosis of either paroxysmal nocturnal hemoglobinuria (PNH) OR atypical hemolytic uremic syndrome (aHUS). Maximum dose: Ultomiris 3.6g every 8 weeks (IV infusion)	One year
UPLIZNA (inebilizumab)	**Uplizna** (inebilizumab) may be approved for members meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member is an adult (≥ 18 years of age) AND has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies AND has a documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) AND • Member has a past medical history of at least one of the following: o Optic neuritis o Acute myelitis o Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting o Acute brainstem syndrome o Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions o Symptomatic cerebral syndrome with NMOSD-typical brain lesions AND • Member does not have active Hepatitis B infection, as confirmed by negative surface antigen [HBsAg] and anti-HBV tests AND • Provider has screened for immunizations the member is due to receive according to immunization guidelines AND any live or live-attenuated vaccines will be administered at least 4 weeks prior to initiation of Uplizna (inebilizumab) AND • Member does not have active or untreated latent tuberculosis AND • For members of child-bearing potential, member is not pregnant or breastfeeding and has been counseled to use effective contraception while receiving Uplizna (inebilizumab) and for at least 6 months after the last dose AND • Uplizna (inebilizumab) is prescribed by, or in consultation with, a neurologist AND • Member will receive corticosteroid, antihistamine, and antipyretic premedication prior to each infusion. Maximum dose: Initial 300 mg IV infusion followed by 300mg IV infusion 2 weeks later, followed by 300mg IV infusion every 6 months (starting 6 months from the initial infusion).	One year
VACCINES	Pharmacies that have entered into a collaborative practice agreement with one or more physicians may receive reimbursement (with claim submission through the Health First Colorado medical benefit) for enrolled pharmacists to administer the following vaccines (claims for pharmacist administration of vaccines are not covered under the pharmacy benefit):	

<table>
<tr><td></td><td>

Covid-19
Influenza
Pneumococcal
Shingles
Tdap
Td

Additional information regarding pharmacist enrollment and vaccine medical claims billing can be found at https://www.colorado.gov/hcpf/otc-immunizations .

Vivotif oral typhoid vaccine may be approved under the pharmacy benefit for out-patient administration.

All other vaccines must be billed on Colorado 1500 form as a medical expense unless administered in a long-term care facility. Pharmacy claims for vaccines administered in a long-term care facility may receive prior authorization approval with verification that the member is residing in a long-term care facility.

Not qualified for emergency 3 day supply PA
</td><td></td></tr>
<tr><td>VALCYTE (valganciclovir hydrochloride)</td><td>
Effective 10/15/19: Brand Valcyte solution is no longer covered as a favored product (see section “Brand Name Medications and Generic Mandate” for brand product coverage details).

Valcyte® will be approved for members with diagnosis of Cytomegalovirus (CMV) retinitis AND acquired immunodeficiency Syndrome (AIDS) per dosing guidelines below
OR
For members that require prophylactic treatment for CMV post kidney, heart or kidney-pancreas transplant per dosing guidelines below
OR
For members ≤ 16 years of age that are at high risk of CMV infection and need prophylactic treatment post heart or kidney transplant per dosing guidelines below

<table>
<tr><th colspan="2">Adult Dosage</th></tr>
<tr><td>Treatment of CMV retinitis</td><td>Induction: 900 mg (two 250 mg tablets) twice a day for 21 days
Maintenance: 900 mg once a day</td></tr>
<tr><td>Prevention of CMV disease in heart or kidney-pancreas patients</td><td>900 mg once a day within 10 days of transplantation 100 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients</td><td>900 mg once a day within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><th colspan="2">Pediatric Dosage</th></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients 4 month to 16 years of age</td><td>Dose once daily within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in heart transplant patients 1 month to 16 years of age</td><td>Dose once a day within 10 days of transplantation until 100 days post-transplantation</td></tr>
</table>
</td><td>One year</td></tr>
<tr><td>VALTOCO (diazepam)</td><td>
Valtoco (diazepam) may be approved for members meeting the following criteria:

Member is 6 years of age or older AND

</td><td>One year</td></tr>
</table>

	• Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern and medical records are provided supporting this diagnosis AND • Member is stable on regimen of antiepileptic medications AND • Medication is being prescribed by or in conjunction with the same provider/provider team who manages the member's anti-epileptic regimen AND • Member is educated on appropriate identification of seizure cluster and Valtoco (diazepam) administration and not to exceed 2 doses per seizure cluster. Maximum dose: 4 nasal spray units per year unless used / damaged / lost Members are limited to one prior authorization approval on file for Valtoco (diazepam) and Nayzilam (midazolam). Grandfathering: If member is currently receiving Valtoco (diazepam) intranasal, they may receive prior authorization approval to continue.	
VELTASSA (patiromer)	**Veltassa** (patiromer) prior authorization will be approved for members that meet the following criteria: • Documented diagnosis of hyperkalemia (serum potassium > 5 mEq/L) AND • Veltassa is not being used for emergent hyperkalemia AND • Member does not have severe gastrointestinal motility dysfunction AND • Member does not have hypomagnesemia (serum magnesium < 1.4 mg/dL)	One year
VERIPRED (prednisolone)	A prior authorization will only be approved if a member has tried and failed on a generic prednisolone product (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.)	One year
VERQUVO (vericiguat)	**Verquvo** (vericguat) may be approved if the following criteria are met: • Member is 18 years of age or older AND • Member is not pregnant AND • Member has a diagnosis of heart failure with reduced ejection fraction (LVEF <45%) AND • Member is not concurrently taking long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, or transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil or tadalafil) AND • Member has a trial and failed ONE agent from EACH of the following drug classes (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions): o ACE inhibitor (such as enalapril or lisinopril) OR ARB (such as valsartan or candesartan) OR angiotensin receptor-neprilysin inhibitor [ARNI] (such as sacubitril/valsartan) o Beta blocker (bisoprolol, carvedilol, metoprolol succinate) o Aldosterone antagonist (spironolactone or eplerenone) o SGLT-2 inhibitor: Farxiga (dapagliflozin), Jardiance (empagliflozin) or Invokana (canagliflozin). Maximum dose: 10 mg/day Quantity limits:	One year

	• 2.5mg: 2 tablets/day • 5mg: 2 tablets/day • 10mg: 1 tablet/day	
VERSED (midazolam) Injection	*Effective 09/25/2019 prior authorization is no longer required for generic midazolam vial/syringe formulations.*	
VILTEPSO (viltolarsen)	**Viltepso** (viltolarsen) may be approved for members meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member must have genetic testing confirming mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 53 skipping AND • Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting Viltepso (viltolarsen). Consider measurement of glomerular filtration rate prior to initiation of Viltepso (viltolarsen) AND • Members with known renal function impairment should be closely monitored during treatment with Viltepso (viltolarsen), as renal toxicity has occurred with similar drugs AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale score or Forced Vital Capacity (FVC) documented AND • Provider and patient or caregiver are aware that continued US FDA approval of Viltepso (viltolarsen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial. Reauthorization: After 24 weeks of treatment with Viltepso (viltolarsen), member may receive approval to continue therapy for one year if the following criteria are met: • Member has shown no intolerable adverse effects related to Viltepso (viltolarsen) treatment at a dose of 80mg/kg IV once a week AND • Member has normal renal function or stable renal function if known impairment AND • Member demonstrates response to Viltepso (viltolarsen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC). Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence. Maximum dose: 80 mg/kg administered as an IV infusion once weekly	Initial: 24 weeks Continued: One year
VIMIZIM (elosulfase alfa)	**Vimizim** (elosulfase alfa) prior authorization may be approved for members meeting the following criteria: • Member is ≥ 5 years of age **AND** • Member has a confirmed diagnosis of mucopolysaccharidosis (MPS) Type IV A (Morquio A syndrome) **AND** • Medication is being administered by a healthcare provider in the member's home or in a long-term care facility (and meets approval criteria listed in "Physician Administered Drug" section of Appendix P) **AND**	One year

	• Vimizim is prescribed by or in consultation with an endocrinologist **AND** • Prescriber acknowledges that Vimizim will be administered under close medical observation due to risk of life-threatening anaphylactic reactions.	
VITAMINS* (prescription vitamins)	**Coverage criteria outlined in this section apply to vitamin products available as prescription drugs. For over-the-counter product coverage, please see "OTC Products" section.* The following prescription vitamin products will be covered without prior authorization: • Vitamin D • Vitamin K **General prescription vitamin criteria: Prescription vitamin products will be approved for: • ESRD, CRF, renal insufficiency, diabetic neuropathy or renal transplant OR • Members under the age of 21 with a disease state or clinical diagnosis associated with prohibited nutritional absorption processes as a secondary effect OR • Members with Erythema Bullosum Hydroxocobalamin injection will be approved for: • Members meeting any general prescription vitamin criteria** OR • Methylmalonic acidemia (MMA) Cyanocobalamin will be approved for: • Members meeting any general prescription vitamin criteria** OR • Vitamin B12 deficiency Folic acid prescription products will be approved for: • Members meeting any general prescription vitamin criteria** OR • Folic acid 1mg will be approved for female members without a prior authorization OR • Members currently taking methotrexate or pemetrexed OR • Documented folic acid deficiency by the treating clinician (megaloblastic and macrocytic anemia are the most common. Some drugs or other conditions may cause deficiency as well) OR • Homocysteinemia OR • Sickle cell disease OR • Female members prescribed folic acid for the prevention of a neural tube defect during pregnancy or for the prevention of miscarriage Cyanocobalamin/folic acid/pyridoxine prescription products will be approved for: • Members meeting any general prescription vitamin criteria** ORMembers meeting any general prescription vitamin criteria* OR • Members with Homocysteinemia or Homocystinuria OR • Members on dialysis OR • Members with (or at risk for) cardiovascular disease For prescription iron-containing products see "Anti-anemia Medications" Metanx will be approved for members with non-healing diabetic wounds	One year

VUSION OINTMENT (miconazole/zinc oxide/white petrolatum)	A prior authorization will only be approved if a member has failed on an OTC antifungal **and** a generic prescription antifungal. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
VYNDAMAX (tafamidis)	**Vyndamax** (tafamidis) may be approved for members meeting the following criteria: • Member is an adult ≥ 18 years of age AND • Member has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloid cardiomyopathy (ATTR-CM) AND • Member has a documented history of heart failure with NYHA functional class I-III Maximum dose: Vyndamax (tafamidis) 61mg daily	One year
VYNDAQEL (tafamidis meglumine)	**Vyndaqel** (tafamidis meglumine) may be approved for members meeting the following criteria: • Member is an adult ≥ 18 years of age AND • Member has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloid cardiomyopathy (ATTR-CM) AND • Member has a documented history of heart failure with NYHA functional class I-III Maximum dose: Vyndaqel (tafamidis meglumine) 80mg daily	One year
VYONDYS 53 (golodirsen)	**Vyondys 53** may be approved if all the following criteria are met: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND • Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 53 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. pediatric neurologist, cardiologist or pulmonary specialist) AND • The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more. Maximum Dose: 30 mg/kg per week	One year
XERMELO (telotristat ethyl)	**Xermelo** (telotristat ethyl) prior authorization may be approved for members meeting the following criteria: • Member is at 18 years of age or older **AND** • Member has a diagnosis of carcinoid syndrome diarrhea **AND** • Member has trialed and failed three months of somatostatin analog therapy (such as octreotide). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Xermelo is being used in combination with somatostatin analog therapy Maximum dose: 750 mg per day	One year
XIFAXAN (rifaximin)	**Xifaxan** (rifaximin) prior authorization will be approved for members meeting the following criteria:	See Criteria

	• For members prescribed Xifaxan for prophylaxis of hepatic encephalopathy (HE) in adults:
	  o Member must be concomitantly taking lactulose or other non-absorbable disaccharide AND
	  o Member must not have undergone transjugular intrahepatic portosystemic shunt (TIPS) procedure within the last 3 months AND
	  o Xifaxan is being prescribed for secondary prophylaxis of HE (member has experienced previous episode of HE) AND
	  o Maximum dosing regimen is 550mg twice daily
	  o Members meeting criteria will receive approval for one year
	• For members prescribed Xifaxan for irritable bowel syndrome with diarrhea (IBS-D):
	  o Maximum dosing regimen is 550mg three times daily for 14 days AND
	  o Approval is limited to <u>two</u> 14-day treatment courses per 14 week time period
	• For members prescribed Xifaxan for traveler's diarrhea:
	  o Member must be ≥ 12 years of age AND
	  o Maximum dosing regimen is 200mg three times daily for 3 days
	  o Members meeting criteria will receive approval for one year	

XOLAIR (omalizumab)	*Note: Injectable omalizumab is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.* **Xolair** (omalizumab) may be approved for members when the following criteria are met: • The member is 6 years of age or older AND • The safety of self-administration has been established by the administration of at least 3 doses of Xolair (omalizumab), without hypersensitivity reactions, under the guidance of a healthcare provider, AND • The prescriber has determined that self-administration of Xolair (omalizumab) by the member or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and implementation of mitigation strategies. <u>Maximum dose</u>: 600 mg every two weeks <u>Quantity Limits</u>: • 75mg/0.5ml: 1 syringe/14 days • 150mg/ml: 4 syringes/14 days	One year

XYREM (sodium oxybate)	**Xyrem** (sodium oxybate) may be approved for <u>adults and children 7 to 17 years of age</u> if all the following criteria are met:
	• Member has a diagnosis of cataplexy or excessive daytime sleepiness with narcolepsy (confirmed by one of the following):
	  o Cataplexy episodes occurring three or more times per month OR
	  o Hypocretin deficiency OR
	  o Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency less than or equal to 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency less than or equal to 8 minutes and two or more sleep-onset REM periods
		Initial Approval: 30 days
		
		Continuation Approval: One year

	AND • Baseline excessive daytime sleepiness is measured using the Epworth Sleepiness Scale or cataplexy episode count AND • Member has adequately trialed and failed therapy with 3 stimulants for narcolepsy (examples include methylphenidate and amphetamine salts) Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interactions. AND • Member must not have recent (within 1 year) history of substance abuse AND • Member is not taking opioids, benzodiazepines, sedative hypnotics (such as zolpidem, zaleplon, eszopiclone, chloral hydrate, etc.) or consuming alcohol concomitantly with Xyrem (sodium oxybate) AND • Prescriber is enrolled in corresponding REMS program AND • If member is an adult (age ≥ 18 years), they have had an adequate trial and failure of therapy with 3 sedative hypnotic medications (examples include zolpidem and eszopiclone). Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions. <u>Initial and Continuation Prior Authorization Approval:</u> Initial prior authorization approval will be for 30 days. For continuation approval for one year, the following information must be provided: • Verification of Epworth Sleepiness Scale score reduction on follow-up OR • Verification of cataplexy episode count reduction on follow-up <u>Maximum Dosing:</u> 9 grams/day	
XYWAV (calcium, magnesium, potassium, sodium oxybates)	**Xywav** (calcium, magnesium, potassium, sodium oxybates) may be approved if the following criteria are met: • Member is ≥ 7 years of age AND • Member has a diagnosis of excessive daytime sleepiness with narcolepsy (confirmed by one of the following): o Hypocretin deficiency OR o Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency less than or equal to 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency less than or equal to 8 minutes and two or more sleep-onset REM periods AND • Baseline excessive daytime sleepiness is measured using the Epworth Sleepiness Scale or cataplexy episode count AND • Member has adequately trialed and failed therapy with 3 stimulants for narcolepsy (examples include methylphenidate and amphetamine salts) Failure is defined as: lack of efficacy with 2 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions AND • Member must not have recent (within 1 year) history of substance abuse AND • Member is not taking opioids, benzodiazepines, sedative hypnotics (such as zolpidem, zaleplon, eszopiclone, chloral hydrate, etc.) or consuming alcohol	Initial Approval: 30 days Continuation Approval: One year

	while receiving Xywav (calcium, magnesium, potassium, sodium oxybates) therapy AND • Prescriber is enrolled in corresponding REMS program AND • If member is an adult (≥ 18 years of age), they have had an adequate trial and failure of therapy with 3 sedative hypnotic medications (examples include zolpidem and eszopiclone). Failure is defined as: lack of efficacy with 2 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions. Initial and Continuation Prior Authorization Approval: Initial prior authorization approval will be for 30 days. For continuation approval for one year, the following information must be provided: • Verification of Epworth Sleepiness Scale score reduction on follow-up OR • Verification of cataplexy episode count reduction on follow-up Maximum Dosing: 9 grams/daily	
YOSPRALA (aspirin/omeprazole)	**Yosprala** (aspirin/omeprazole) will be approved for members who meet the following criteria: • Member requires aspirin for secondary prevention of cardiovascular or cerebrovascular events **AND** • Member is at risk of developing aspirin associated gastric ulcers (member is ≥ 55 years of age or has documented history of gastric ulcers) **AND** • Member has failed treatment with three preferred proton pump inhibitors in the last 6 months (Failure is defined as: lack of efficacy of a seven-day trial, allergy, intolerable side effects, or significant drug-drug interaction).	One year
ZOKINVY (lonafarnib)	**Zokinvy** (lonafarnib) may be approved if the following criteria are met: 1. Member is one year of age or older **AND** 2. Member has a body surface area of 0.39 m^2 or greater **AND** 3. Member has one of the following diagnoses: a. Hutchinson-Gilford Progeria Syndrome (HGPS) confirmed by genetic testing for the pathogenic variant in the LMNA gene that results in production of progerin b. Processing-deficient progeroid laminopathy confirmed by genetic testing for heterozygous LMNA mutation with progerin-like protein accumulation **OR** for homozygous or compound heterozygous ZMPSTE24 mutations **AND** 4. Member is not taking lovastatin, simvastatin, or atorvastatin **AND** 5. Member, parent, or legal guardian has been, or will be, counseled that Zokinvy (lonafarnib) may impact pubertal development and impair fertility **AND** 6. Zokinvy (lonafarnib) is being prescribed or in consultation with a specialist in the area of the patient's diagnosis (such as a cardiologist or geneticist). Maximum dose: 300 mg/day Quantity limit: 4 capsules/day	One year